EXHIBIT H

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327
	MDL NO. 2327
THIS DOCUMENT RELATES TO: DIANNE M. BELLEW, Case No. 2:13-cv-22473	JOSEPH R. GOODWIN US DISTRICT JUDGE

- - -

November 10, 2014

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Videotaped deposition of PROF. DR. MED. UWE KLINGE, held at Quellenhof Hotel, Monheimsallee 52, 52062, Aachen, Germany, commencing at 9:04 a.m., on the above date, before Tami Cline, Registered Merit Reporter, Certified Realtime Reporter.

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THE VIDEOGRAPHER: We are now on the record. My name is Gregory Fields. I'm the videographer for Golkow Technologies. Today's date is 11/10/2014, and the time is 9:04 a.m. This video deposition is being held in Aachen, Germany, in the matter of In Re: Pelvic mesh, for the Superior Court of New Jersey, Atlantic County. The deponent is Uwe Klinge. Counsel will be noted on the stenographic record. The court reporter is Tami Cline and will now swear in the witness.

MR. THOMAS: The court reporter noted that the taped deposition was being taken in the Superior Court of New Jersey. I thought this was an MDL deposition.

THE VIDEOGRAPHER: I'm sorry. I had that as a --

MR. ANDERSON: MDL deposition.

THE VIDEOGRAPHER: This is the MDL?

MR. ANDERSON: Yeah.

THE VIDEOGRAPHER: I apologize.

MR. THOMAS: And only the MDL. It's not cross-noticed in New Jersey.

MR. ANDERSON: It's MDL.
THE VIDEOGRAPHER: Okay. Okay.
THE COURT REPORTER: Would you raise your right hand, please.
Do you swear or affirm the testimony you give in this cause will be the truth, the whole truth and nothing but the truth?
THE WITNESS: I swear.
THE COURT REPORTER: You can put your hand down.
PROF. DR. MED. UWE KLINGE, called as a witness by the Plaintiff, having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. ANDERSON:

Q. Good morning, Dr. Klinge.
A. Good morning.
Q. Dr. Klinge, please tell the jury what your profession is.
A. I'm an abdominal surgeon and a biomaterial researcher.
Q. Where do you work, Dr. Klinge?
A. I'm working at the University of Aachen.
Q. And is that Aachen, Germany?

A. It's Aachen, Germany.
Q. And is that where we are today?
A. Exactly.
Q. Please tell the jury a little bit about Aachen University Hospital.
A. It's a large teaching and research hospital, and it is -- it has an extended research center dealing with medical devices, the development of medical devices.
Q. And would those medical devices include surgical meshes like the Prolift mesh?
A. Yes.
Q. And before we go through the issues in this case, would you please just tell the jury briefly about your education and training as a surgeon?
A. I started my medical training 1977 at this university, and when I finished it, then I started to work in the surgical department at this university for almost now -- almost 30 years. Yeah.
Q. And did you do a surgical residency?
A. Yes.
Q. What years did you do a surgical residency?
A. It started in 1985, and I worked specified as abdominal surgeon -- as a general surgeon in 1993,

and some years later on I got specified as an abdominal surgeon.
Q. Tell the jury a little bit about your practice of abdominal surgery.
A. While working at this surgical department, I performed some thousands of operations, mainly done for diseases of the abdominal cavity of the intestine of the abdominal wall, but it covers almost all parts of the body.
Q. Have you used synthetic surgical mesh in your surgical practice?
A. Yes, I did.
Q. Did you use hernia meshes in your surgical practice that were manufactured by Ethicon?
A. Yes, I did.
Q. Doctor, what caused you to study the biomaterial science of surgical meshes?
A. When we started to use surgical meshes in the beginning of the '90s, we got aware that we have to face several complications that are related with these mesh materials, mainly at the occasion of some revision operations where we saw what happens to these meshes after getting incorporated; and we wanted to learn more about these meshes to avoid

these complications.
Q. And when did you first begin that work?
A. We started to think about it in the beginning of the '90s, and the research project really started in 1994.
Q. And as part of your work in looking at the biomaterial science of surgical meshes and trying to relate those to complications, did you work as a consultant for Ethicon?
A. Yes, indeed. When we decided to study meshes and wanted to know what is the impact of the meshes to the damage in the tissue, it was necessary to collaborate with the manufacturer, because for these research, you need a lot of modifications. You need a lot of different designs to find out what is the impact of a specific design to the tissue response. And we have been very happy to find Ethicon as a partner in this research who, during the following ten years, supplied us with a lot of these meshes and a lot of modifications so that we can do all these studies.
Q. And was this collaboration between Aachen University Hospital, where you are here in Aachen, and Ethicon?

A. Yes.
Q. Okay. Dr. Klinge, all of your opinions today will need to be to a reasonable degree of medical and scientific certainty. Do you understand that?
A. Yes.
Q. Have you published articles in the peer-reviewed medical literature that relate to the safety of surgical meshes either for the abdomen or the pelvic floor?
A. Yes, I did.
Q. How many times?
A. With the specific topic of surgical meshes, it's more than 100.
Q. Have you written books and book chapters that relate to the safety of surgical meshes for both the abdomen and the pelvic floor?
A. Yes, I did.
Q. And on how many times?
A. About 50.
Q. Have you been asked to speak at conferences around the world on the topic of surgical mesh complications and safer mesh design for the abdomen and the pelvic floor?
A. Yes, I have been, and I'm still.

Q. Have you been asked by Ethicon to speak as an invited lecturer at conferences sponsored by Ethicon?
A. Yes.
Q. On how many occasions?
A. Several dozens.
Q. Have you been invited by Ethicon to speak directly to urogynecologists and urologists regarding surgical meshes for the pelvic floor?
A. Yes, I was.
Q. Doctor, what is Prolene mesh?
A. Prolene mesh is the brand name of a mesh, a plastic net made of polypropylene fibers.
Q. And is there a particular manufacturer that uses the brand name Prolene?
A. It's a brand name from Ethicon.
Q. Are you familiar with the term "Prolene Soft Mesh"?
A. Yes.
Q. And what is Prolene Soft Mesh?
A. It is, again, a brand name from a mesh from Ethicon made of polypropylene fibers.
Q. And you're familiar with the word -- the mesh Gynemesh PS?
A. Yes. It is -- it is the same textile

structure as for Prolene Soft.
Q. So Prolene, Prolene Soft and Gynemesh PS, is it your testimony they are all brand names for polypropylene mesh made by Ethicon?
A. Yes.
Q. Okay. What is the mesh material that's in the Prolift device?
A. It is polypropylene.
Q. And what is the brand name from Ethicon for this polypropylene in the Prolift device?
A. It's Gynemesh PS.
Q. Okay. Have you reviewed and do you rely upon Ethicon internal documents and depositions of Ethicon witnesses that you reviewed over the course of this case in arriving at your opinions that you are going to offer here today?
A. Yes.
Q. With regard to the Prolift, are you familiar with the weight and surface area, the weave pattern and the pore size --
A. Yes.
Q. -- of Prolift mesh?
A. I'm sorry.
Q. All right.

A. Yes, I am.
Q. Generally speaking, how is the Prolift supposed to function?
A. It is supposed to function as a flat layer reinforcing the tissue and the pelvic floor.
Q. Dr. Klinge, I would like to talk to the jury now about the way the tissue in our bodies reacts to a foreign substance like polypropylene. Now, with your help and at your request, did we prepare some slides for the jury today?
A. Yes.
Q. And would you feel that those would be helpful to you as we are talking about some of your opinions with the jury?
A. Yes.
MR. THOMAS: Let's go off the record a second, please.
THE VIDEOGRAPHER: We are off the record. The time is 9:13 a.m.
(A recess was taken from 9:13 a.m. until 9:14 a.m.)
THE VIDEOGRAPHER: We are back on the record. The time is 9:14 a.m.
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(Plaintiff's Demonstrative Exhibit No. P3358,

PowerPoint slide titled "Foreign Body Reaction: More Foreign Body = More Inflammation," Bates stamped P1005 ETH.MESH.02341454, marked for identification.)

BY MR. ANDERSON:

Q. Doctor, I'm showing you the first slide, which is a demonstrative exhibit, which we have gone ahead and labeled as Plaintiff's Exhibit P3358. Is this slide entitled, "Foreign Body Reaction," a slide that you helped prepare for the jury today?

A. Yes.

Q. What does foreign body reaction refer to?

A. Foreign body reaction mainly consists of an inflammatory reaction and a scar reaction. And if you -- assume you get a splinter or foreign body into your tissues. The body tries to get rid of it, and if they -- if the body is not able to get rid of this foreign body, it's sent a lot of white blood cells to this to build a wall to protect the surrounding tissue from this foreign body. And this inflammatory -- these inflammatory cells are then surrounded by dense scar tissue.

Q. And when we see on this slide "more foreign body equals more inflammation" -- you have put that

there. Why have you put that there for the jury?

A. Sorry?

Q. "More foreign body equals more inflammation," why have we put that there? Why is that significant to your opinions, Doctor?

A. Yeah. It was one of our -- or it was confirmed by all of our studies that, of course, the more foreign body you have, the more inflammation you have. The more surface you have, the more inflammation you have. So if you have two splinters, you will have more inflammation than if it is only one.

Q. Doctor, I believe by this time in the trial that the jury would have already seen a Prolift anterior mesh. I -- we have one there on the slide. Did I ask you to calculate the amount of polypropylene fiber that is woven into a Prolift anterior mesh?

A. Yes, I did.

Q. And please tell the jury how much polypropylene suture material is in a Prolift anterior mesh.

A. So it is -- it is about 240 meters of polypropylene fiber that is used in the Prolift

anterior implant.

Q. Doctor, did I ask you to bring with you to your testimony today a Prolene suture?

A. Yes.

MR. ANDERSON: And, Counsel, for purposes of the record, it's a demonstrative exhibit, which we have premarked as Plaintiff's Exhibit P3363.

(Plaintiff's Exhibit No. P3363, Prolene suture, was marked for identification.)

BY MR. ANDERSON:

Q. Doctor, is this the Prolene suture you brought here to the deposition today?

A. Yes. Exactly.

Q. Can you please first show the Prolene suture to the jury? If you would just lay it on that piece of paper so the -- our kind videographer here can pick up on that.

A. (Complying.)

Q. Thank you.

Now, Doctor, you have placed sutures like this in patients?

A. Yes. This is a typical suture we are using

in the OR, but usually we made some knots about it and we removed the rest of the fibers. So, actually, we left 1 to 2 centimeters of this suture in the body when we made a stitch with this material.

Q. So given that you trim this after you do the stitch, show the jury, if you would, how much polypropylene stitch is left.

A. So, of course, it depends from thickness of the tissue, but usually it's not more than this.

Q. What is that?

A. What remains in the tissue after --

Q. About 2 inches?

A. An inch is 2.5 centimeters, so it is -- it is less than one inch.

Q. Okay. By way of example, Doctor, did I ask you to measure -- you said there was 240 meters of polypropylene material in an anterior mesh?

A. Yes.

(Plaintiff's Exhibit No. P3364, 240 meters of polypropylene, marked for identification.)

BY MR. ANDERSON:

Q. I will mark this as Plaintiff's

Exhibit P3364. Did I ask you to measure out 240 meters of polypropylene?

A. Yes. I --

Q. Could you, please -- and did you measure that yourself?

A. Yeah. I did it myself, and I actually walked 20 times in my room or at my house --

Q. Okay.

A. -- to get this -- the length of this suture material.

Q. If you would just lay that on the piece of material next to it.

A. Yeah.

Q. Now, Doctor, we're not as familiar in the United States with the metric system. How many yards of material does 240 meters relate to?

A. It is equal to 260 yards.

Q. And you know in the US we play football, and a football field is 100 yards long. So is this more than two and a half football fields of material that's woven into a Prolene anterior mesh?

A. Exactly. Or if you don't play football, it is three times the height of the Statue of Liberty in New York.

Q. Okay. All right. Thank you.

Doctor, do you have an opinion to a reasonable degree of medical and scientific certainty as to whether there will be a different amount of foreign body reaction and inflammation in a patient's tissues to less than one inch of suture material of polypropylene versus more than two and a half football fields of polypropylene material? Do you have an opinion?

A. Yes.

Q. And what is that opinion?

A. If you place this huge amount of material in a comparatively small area, you will have a significantly higher intensity and amount of inflammation and scar tissue as a reaction to this huge amount of material.

Q. Okay. Doctor, we can put those to the side for the moment.

I would like to now -- sorry. I would now like to talk to you about the relationship between this foreign body reaction to polypropylene mesh and a concept known as mesh contraction or mesh shrinkage. Are you familiar with those terms, mesh shrinkage or mesh contraction?

A. Yes.

Q. Just briefly tell the jury in your own words what mesh contraction or mesh shrinkage is.

A. When we are talking about mesh shrinkage, we usually are thinking of the contraction of the scar tissue around the mesh.

Q. And is scar tissue -- is there another -- is fibrosis also another word for scar tissue?

A. Yes. Fibrosis is -- the fibrosis around the mesh is usually the scar tissue.

Q. So if this piece of paper is the mesh as it's in the body, can you explain to the jury what we're talking about in terms of mesh shrinkage or contraction if that's the implant and the black here is -- the table is the tissue?

A. When the mesh is usually incorporated into the scar tissue, and we know that scar contracts. It lose a lot of water, and, therefore, when the scar is contracting, it is pushing together the implant like this. It can be up to 90 percent that the mesh material is reduced by this contraction of the scar.

Q. Have you published in the peer-reviewed literature on the subject of mesh shrinkage and contraction and the resulting clinical consequence to

patients?

A. Yes, I did.

Q. How many publications over what period of time relate to mesh shrinkage and mesh contraction that you have authored?

MR. THOMAS: Objection, without more specificity into what area of the body.

BY MR. ANDERSON:

Q. Doctor, have you published in the peer-reviewed literature on the subject of mesh shrinkage and contraction of polypropylene meshes, like the Prolift mesh, resulting in clinical consequences to patients?

A. Yes.

MR. THOMAS: Same objection.

BY MR. ANDERSON:

Q. How many times have you done that, Doctor?

A. It's more than 50.

Q. Doctor, in terms of inflammatory response and this foreign body reaction that we have been talking to, will that -- will there be any difference between a surgical mesh implanted, for instance, in the abdominal wall and these principles versus a surgical mesh implanted in the pelvic floor?

MR. THOMAS: Objection; foundation.
THE WITNESS: The wound contraction is not restricted to the abdominal wall. It happens in the entire body. The foreign body responds. The scarring around a foreign body happens in every part of the body, and in this regard the response of the tissue to the -- to a mesh, it's quite similar whether it is in the pelvic floor or whether it's in the abdominal cavity.
BY MR. ANDERSON:
Q. Doctor, I now want to explain to the jury what the consequences to the patient are of severe inflammation and contraction of polypropylene mesh like Prolift. Okay?
A. Yes.

(Plaintiff's Exhibit No. PLT0067, Article entitled "Complications from vaginally placed mesh in pelvic reconstructive surgery", was marked for identification.)

BY MR. ANDERSON:
Q. I'm handing you what has been marked as Plaintiff's Exhibit 0067. It is PLT0067.

MR. THOMAS: This has a sticky on it. Is that yours?
MR. ANDERSON: What I have done for you, Counsel, is on every one of these documents, since they're multipaged, to make it easier for you to reference them, I flagged the pages for you.
MR. THOMAS: Thank you.
MR. ANDERSON: You're welcome.
BY MR. ANDERSON:
Q. Do you recognize this article as something you reviewed in arriving at your opinions in this case?
A. Yes.
Q. And it says -- is this article from the International Urogynecological Journal in 2009 significant to your opinions in this case?
A. Yes, it is.
Q. If you will please turn with me to page 529.
MR. ANDERSON: And if you'll highlight -- Michael, if you'll highlight the bottom right image.
BY MR. ANDERSON:
Q. Doctor --

MR. THOMAS: Just note my objection to this before you show the jury what the picture is until we have an adequate foundation for the jury to see the picture.
BY MR. ANDERSON:
Q. And you reviewed this article in coming to your opinions in this case?
A. Yes.
Q. And does this article involve the Prolift mesh?
A. Yes.
Q. And if we're looking at this image contained within the article, what are we looking at here, Doctor?
A. It is showing the explanted mesh material that is in -- taken off in several parts, and you see that it is incorporated into a lot of scar tissue, that it is deformed, that it's not laying very flat in this area.
MR. THOMAS: Just show --
THE WITNESS: It's hard to identify the textile structure in this compound of scar.
MR. THOMAS: I just want to show my continuing objection for lack of foundation.

MR. ANDERSON: Noted.
BY MR. ANDERSON:
Q. As a hernia surgeon, did you remove contracted polypropylene meshes from patients?
A. Yeah. We did a lot. And the appearance of these meshes are completely similar to this. We have -- in these contracted meshes, we have this huge amount of scar tissue. The advantage in the abdominal wall is that we are able to explant them in total and, whereas in this area, it usually is taken off in parts.
Q. And you say, "in this area." You removed mesh from the pelvic floor?
A. Yes.
Q. Did you have an opportunity to review Dr. Howard Jordi's expert report in this case?
A. Yes.
Q. Did you see photos in his report of mesh that had been taken out of Ms. Bellew?
A. Yes.
Q. And did you rely on those photos in his report in arriving at your opinions here today?
A. Yes.
MR. THOMAS: Objection. To my knowledge,

the -- any specific causation testimony of Ms. Bellew is not contained in his report. Am I incorrect?

MR. ANDERSON: We're not going to talk about causation.

MR. THOMAS: Okay. Show my objection to any plaintiff-specific testimony by Dr. Klinge.

MR. ANDERSON: I'll show your objection.

(Plaintiff's Exhibit No. P3356, Page 20 of 1386 from Howard Jordi's expert report containing photographs, was marked for identification.)

BY MR. ANDERSON:

Q. I'm handing you what's been premarked as Plaintiff's Exhibit 3356. Is that one of the photographs that you saw from Dr. Jordi's report of explanted mesh from Ms. Bellew?

A. Yes, it is.

Q. Was this image significant to your opinions in this case?

A. Yes.

Q. Can you please explain the significance of that image in relation to what we just -- what the

jury just saw?

A. This image --

MR. THOMAS: Excuse me. Let me place my objection. I object to this because it is not a disclosed opinion in the report that Ben here -- that's at issue in this deposition and also because this witness is designated on general causation issues and not on plaintiff-specific issues.

BY MR. ANDERSON:

Q. Does the appearance of Ms. Bellew's contracted mesh in -- does the appearance of the mesh in -- from Dr. Jordi's report -- what do you see from that -- from that image, sir?

A. On this photograph you see the folding of a mesh that is incorporated into very big amount of scar tissue, and it is a confirmation that this phenomenon is not limited to the abdominal wall, but it happens in every part of the body.

Q. Now, Doctor, you have seen the Prolift anterior mesh as it comes out of the box? Have you seen that?

A. Yes.

Q. How does the Prolift mesh out of the box

compare to contracted mesh removed due to complications like we've seen in these -- in these recent photographs from the Blandon article as well as this from Ms. Bellew?

A. The mesh, when it's taken out of the box, usually is very soft, pliable, flexible, whereas a mesh that is integrated into this scar tissue usually is rigid, stiff, not flexible, not stretchable any longer; and, therefore, it is going to be in sharp contrast to the properties of the surrounding tissue.

Q. Doctor, did you prepare a slide for the jury regarding mesh inflammation and contraction and their relation to consequences for the patient?

A. Yes.

(Plaintiff's Demonstrative Exhibit No. P3359, PowerPoint slide entitled "Patient Injury Due to Mesh Inflammation and Contraction", was marked for identification.)

BY MR. ANDERSON:

Q. I'm showing you what we have marked as Plaintiff's Exhibit P3359. Is that the slide?

A. Yes.

Q. Okay.

MR. ANDERSON: If you could just bring in the first bullet points.

MR. THOMAS: Just show my objection to this demonstrative and testimony about this because the patient has not been designated for the quantitative risks of complications in the pelvic floor.

BY MR. ANDERSON:

Q. Doctor, if we look here to these first two bullet points, can you tell us why you created these for the jury?

A. One of our important findings in these years of research together with Ethicon was that this mesh inflammation, this inflammatory region around the foreign body, it's a permanent one. It is -- it doesn't stop after three weeks or four weeks, but it stays there as a chronic wound until the end of the life of the patient; and this chronic wound leads to a permanent tissue irritation.

In some patients there's always some sort of scarring that is protecting the surrounding tissues from the foreign body, but in some patients this scarring is very, very severe; and it leads that

almost all the entire area where the mesh was been placed is blocked by this scarring.

MR. THOMAS: Just show my objection to any testimony to Bullets 2, 3 and 4 because it calls for testimony about risks in the pelvic floor which is beyond this witness's expertise.

BY MR. ANDERSON:

Q. Doctor, over the course of your 20 years of research, how many explants from the abdominal wall have you looked at and analyzed?

A. We have meanwhile several thousand of explanted meshes here that we have had a look to and we try to analyze.

Q. As part of this body of work over the last 20 years, how many explanted meshes from the pelvic floor have you analyzed?

A. It's up to 500.

Q. Okay. So with regard to these thousands of hernia mesh explants from humans that you have analyzed and hundreds of pelvic floor explants that you've analyzed over the course of these 20 years, have you recognized similarities between the contraction of the explanted abdominal wall meshes and the explanted pelvic floor meshes?

MR. THOMAS: Show my objection to this to the extent it's based upon his review of the Klosterhalfen explants of the pelvic floor which this court has already ruled is inappropriate for him on which to rely for his opinions.

MR. ANDERSON: Counsel, how about just saying "objection"?

MR. THOMAS: Because I didn't think it would be clear from the record.

BY MR. ANDERSON:

Q. Have you personally reviewed pelvic floor explants?

A. Yes.

Q. How many personal -- how many personal reviews of pelvic floor explants have you done, Dr. Klinge?

MR. THOMAS: Same objection.

THE WITNESS: It's about 50.

BY MR. ANDERSON:

Q. Okay. So of these 50 meshes that have been taken out of women's bodies that you've analyzed and the hundreds, if not thousands, that you've looked at of hernia mesh explants, have you noticed similarities in terms of the tissue response to the

polypropylene meshes that have been explanted?

A. We always found similar tissue response, and we didn't find any significant difference in the tissue reaction.

Q. And with regard to the first two bullet points on the slide that we were talking about a few minutes ago, mesh inflammation is permanent and in some patients mesh scarring is severe. Have you arrived at those opinions based upon your 20 years of work, all of your peer-reviewed publications, the conferences you've spoken at around the world, the conferences to urogynecologists and urologists at the request of Ethicon, your review of thousands of hernia mesh explants and your review of hundreds of pelvic floor explants and over 50 that you have reviewed yourself?

MR. THOMAS: Objection.

THE WITNESS: Yes, exactly.

MR. THOMAS: Object to the form of question.

THE WITNESS: It is.

MR. ANDERSON: Whatever.

BY MR. ANDERSON:

Q. Go ahead.

A. The permanence of the mesh inflammation, it's

a fact and that in some of these cases you have an extended scarring. It is a fact. It is not related to some specific location in the body.

MR. ANDERSON: Okay. Let's show the next two bullet points.

BY MR. ANDERSON:

Q. Doctor, based upon your review of all of the Ethicon materials and the Ethicon depositions, your review of the scientific literature in this case, your 20 years of experience as a biomaterials researcher, your experience as a hernia surgeon who's treated -- not only implanted but treated complications related to hernia, your review of thousands of hernia mesh explants, your analysis personally of 50 pelvic floor explants, and all of the work that you've done to arrive at your opinions in this case, can you state to a reasonable degree of medical and scientific certainty as to whether or not these two bullet points here are accurate?

MR. THOMAS: Object to the form. Object; goes beyond his expertise and beyond his designation in the report.

THE WITNESS: Yes. It is -- it is a fact that if you have a chronic wound with a lot of

scar tissue, that, of course, you have a higher risk for chronic pain, because of a higher risk for getting nerves that are entrapped into the scar tissue; and in the area of the pelvic floor you have a higher risk of dyspareunia, erosions and organ dysfunction. And, therefore, the extent of inflammation and scarring is a very big concern for the patient's safety. And if you have a lot of inflammation, a lot of scar, this carries a lot of risks for the patients.

BY MR. ANDERSON:

Q. Is there any way for a surgeon who is implanting a Prolift mesh or a hernia mesh to know the extent of scarring and contraction that will occur over the patient's life in and around the mesh or a way to control it?

A. Not in regard to the specific response of a patient, but for the general statement that the more material, the more inflammation, then, of course, you can estimate it.

Q. Based upon your years of consulting with Ethicon and all of your work over the last 20 years, and your work with Ethicon, do you have personal knowledge as to whether Ethicon was aware of these

issues with contraction and inflammation of their polypropylene meshes that you have discussed?

MR. THOMAS: Objection to what Ethicon knew.

BY MR. ANDERSON:

Q. Again, based upon your personal knowledge as a consultant with Ethicon, did you have discussions with them about the contraction of their polypropylene meshes?

A. Yes, I definitely know that we have discussed this during our working group meetings with people from Ethicon, exactly this problem of shrinkage, and we have been trying to figure out what are the main reasons. So, yeah, it was a finding from Ethicon as well as from us --

Q. And did you --

A. -- working hand in hand.

Q. I'm so sorry.

And in this working hand in hand with Ethicon in coming to these questions regarding mesh shrinkage and its relationship to patient complications, did you publish, while you were a consultant with Ethicon, in the peer-reviewed literature on these issues?

A. Yes.

Q. Are these documents significant to your opinions -- strike that.

Have you seen in the internal documents and depositions of Ethicon witnesses discussions regarding patient complications related to mesh contraction?

A. Yes.

Q. Are these documents significant to your opinions in this case?

A. Yes.

Q. Have you studied and published in the peer-reviewed literature on the amount of shrinkage or contraction that will occur in the human body to polypropylene surgical meshes?

A. Yes.

Q. What have your studies shown regarding the amount of shrinkage that occurs with polypropylene meshes in the human body?

A. Roughly you have to estimate a shrinkage, a contraction of about 30 to 50 percent, but it depends on the design of the mesh. So it can be much more; it can be a little bit less.

Q. How does the amount of foreign body material in the mesh relate to the amount of mesh shrinkage or

contraction that will occur in the tissue?

A. The more material, the more inflammation, the more scar, the more contraction, the more shrinkage.

Q. Dr. Klinge, in the internal documents that you have reviewed from Ethicon, have you seen anywhere where they mention or address these concerns over the amount of material with their Prolift mesh?

A. Yes, I did.

(Plaintiff's Exhibit No. P0036, PowerPoint presentation entitled "Stand & Deliver - Pelvic Floor Repair", was marked for identification.)

BY MR. ANDERSON:

Q. I'm showing you what has been marked as Plaintiff's Exhibit P0036.

Is this document something that you have reviewed during your work in this litigation?

A. Yes, I did.

Q. Is it significant to your opinions in this case?

A. Yes.

MR. THOMAS: What is the date of this document?

MR. ANDERSON: It's in your production, and so any Ethicon production, according to the metadata, I believe it's 2008, but we can certainly check that on a break.

MR. THOMAS: Thank you. Just note my objection to the use of any company documents after the date of Mrs. Bellew's surgery.

MR. ANDERSON: Oh, this is certainly before Ms. Bellew's surgery.

MR. THOMAS: I just wanted to make sure. Thank you, Ben.

BY MR. ANDERSON:

Q. Is this document significant to your opinions in this case?

A. Yes.

Q. Just explain briefly what this document is, Dr. Klinge.

A. It's a PowerPoint presentation from Ethicon.

Q. Okay. If you go to page 7 of the document in this Ethicon PowerPoint, you have seen this slide?

A. Yes.

Q. Okay. Is this important to your opinions?

A. Yes, it is important.

Q. Can you explain why, please?

MR. ANDERSON: Blow up the -- yes.

THE WITNESS: The topic of this slide is "Improved Tissue Response," and so to get an improved tissue response, the people that make this presentation, they cited my work with Klosterhalfen --

MR. ANDERSON: If you could blow that up.

THE WITNESS: -- where we wrote down the entire concept of the lightweight and large pore concept, and they figured out that for an improved tissue response, you need a large porous construction to reduce the tissue response. So they are in line completely with what we have found during these years, and they accepted it, obviously.

BY MR. ANDERSON:

Q. And is this in line -- how does this relate to your opinions regarding the amount of foreign body reaction and the amount of inflammation?

A. It's exactly in accordance. So, yeah.

(Plaintiff's Exhibit No. 1156, PowerPoint presentation entitled "T-Pro (Thunder) - Pipeline Leadership Team (PLT) - State Gate Discovery Initiation, August 25, 2008, was marked for identification.)

BY MR. ANDERSON:

Q. Okay. I'm showing you what has been marked as Plaintiff's Exhibit 1156.

Are you familiar with this document, Dr. Klinge?

A. Yes, I am.

Q. Is this something that you reviewed during your work in this litigation?

A. Yes, I did.

Q. And is it significant to your opinions here today?

A. Yes, it is.

Q. If we turn to page 12 of the document, is this slide significant to your opinions?

A. Yes.

MR. ANDERSON: Can you blow up the right-hand side of that?

BY MR. ANDERSON:

Q. Doctor, is this part of the PowerPoint slide significant? And, if so, why?

A. In this PowerPoint presentation from 2008

from Ethicon, it is clearly stated that we need less foreign body material. We need materials that correlate to the physiological characteristics. So it expresses that these people want to have less material to make it safer.

Q. Based upon your review of all of the materials in this litigation and all the depositions as well as your years of consulting with Ethicon, did you determine whether or not they ever manufactured a pelvic organ prolapse mesh with mesh that was actually designed for the pelvic floor?

A. No, I didn't -- didn't find any -- any information to this.

Q. The Gynemesh PS mesh and Prolift, was that designed by Ethicon as a hernia mesh or a pelvic floor mesh?

A. To my knowledge, it was designed as a material-reduced hernia mesh.

Q. Okay. Dr. Klinge, I want to shift gears here a little and talk to you about another mesh design characteristic, and that is the pores. What are mesh pores?

A. A mesh is more or less a net, and the pore is the area in between the filaments.

Q. Is the size of the pores or these open spaces in the mesh material something that you have studied over the last 20 years, published on in the peer-reviewed literature, consulted with Ethicon about and presented at conferences around the world over the last 20 years?

A. We did it extensively.

Q. Is it also these open spaces or these pores a design principle that you have used to work with manufacturers to design safer meshes?

A. Yes.

Q. Can you tell us what the significance of these pores or open spaces are with regard to the tissue response for patients?

A. The size of a pore means a critical parameter to predict what happens when the tissue is -- or when the mesh is incorporated into the tissue. If you have very small pores, then the -- or the space in between the fibers is completely filled by scar tissue; and that makes the mesh stiff and rigid, whereas if you have very large pores, large distances between the fibers, the body is able to fill the pores with fat tissue, and then the mesh remains flexible, stretchable. So the small pores means a

considerable risk for the patient, whereas the larger the pore, the less of the risk.

Q. Is another way to say the larger the pore, the greater the distance between the fibers of the mesh?

A. Yes.

Q. Okay. Have you conducted research over the last 20 years, published peer-reviewed studies, and worked as an Ethicon consultant on sufficient pore size or how large these openings need to be in surgical meshes to prevent these patient consequences you are talking about?

A. Yes, we did.

Q. And has that research included analyzing the pore size of meshes that are surgically removed from animal models, abdominal wall, as well as the pelvic floor?

A. Yes.

Q. And from your background, training, research, your peer-reviewed publications, all your work for the past 20 years. Your consulting work with Ethicon, all the materials that you have reviewed in this case, do you have an opinion to a reasonable degree of medical and scientific certainty as to what

the critical pore size or open space must be for a surgical mesh implant for both hernia repair and pelvic floor repair in order to be safe in the tissues?

A. Yes.

Q. And what is that opinion?

A. The larger the pores, the safer it is to -- the larger the pores, the lower the risk for this bridging; and for polypropylene, the critical figure is about 1 millimeter.

Q. And, again, we're on the metric system, but I know the jury is going to see documents that some of them are in millimeters and some are microns. What does 1 millimeter equal in terms of microns?

A. It equals 1,000 microns.

Q. So 1 millimeter equals 1,000 microns?

A. Yes.

Q. So would -- I'm not real good at math, so would 3 millimeters equal 3,000 microns?

A. Exactly.

Q. Okay. I got that one right.

I know that you said you have over 1,000 publications in the peer-reviewed literature on the safe design of surgical meshes. We obviously can't

go through all of those today, but I did want to show the jury just a couple of your peer-reviewed publications contained in your research on the relationship between inflammation and contraction and adequate mesh pore size for polypropylene meshes. Okay?

A. Yes.

(Plaintiff's Exhibit No. PLT0260, Article entitled "Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model", was marked for identification.)

BY MR. ANDERSON:

Q. I'm showing you what we have marked as Plaintiff's Exhibit PLT0260.

MR. ANDERSON: Counsel.

If you'll highlight the top.

BY MR. ANDERSON:

Q. Is this one of your peer-reviewed publications on polymer pore size?

A. Yes, it is.

MR. ANDERSON: And if we could turn to page 213 and enlarge the left side of the

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document down there where it says "loose network."

BY MR. ANDERSON:

Q. Doctor, drawing your attention to this part of your peer-reviewed publication from 2002, what does that statement tell us in terms of this relationship between these -- the distance between the fibers and patient complications?

A. In this publication from 2002, we described that we found that if you have larger pores of more than 1, 2 millimeters, then the scar tissue is limited to the fibers and that the pores, the holes in between the fibers, are filled by fat tissue. So these are the good pores, whereas if you have smaller pores, less than 1 millimeter, you usually have scar tissue linking these fibers strongly to each other and making the entire implant stiff and rigid.

Q. And just to be clear, Doctor, does that mean that every pore from an explanted mesh that is less than 1,000 microns, that every one of them is going to be filled with scar?

A. No. But the risk is very, very high that these pores are filled by scar tissue; and, therefore, you have to say, the larger the pore, the

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lesser the risk.

Q. So the higher the -- the further the distance of the fibers above 1,000 microns, the less risk of this bridging of the scar tissue?

A. Yeah, less risk and make it more safer, then, for the patient.

Q. Okay. And if we could just turn to the last page.

Who funded this study that you did regarding impact of polymer pore science?

A. These findings were part and as a result of our collaboration in these ten years where we worked together with the people from Ethicon.

(Plaintiff's Exhibit No. PLT0271, Article entitled "The lightweight and large porous concept for hernia repair", was marked for identification.)

BY MR. ANDERSON:

Q. I'm now handing you what has been marked as Plaintiff's PLT0271.

Do you recognize this as another one of your peer-reviewed publications?

A. Yes.

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Q. And in this 2005 article, does it discuss your research on inflammation and scarring and its relationship to adequate pore size?

A. Yes.

MR. ANDERSON: If we go to the second page of the article and we blow up this left side, if you could draw up some language there and do the photograph underneath it as well. Thank you, Michael.

BY MR. ANDERSON:

Q. Explain to the jury if this has any significance to you in this relationship of pore size of a mesh and patient complications.

A. So this manuscript basically is a summary of these ten-year works.

Q. Ten-year work with Ethicon you mean?

A. With Ethicon where we wanted to develop safer meshes together with them. And you see an example of small pore meshes on the left side with the number "A" there. These are very small pores, and these are all filled up by scar tissue, making this rigid mesh scar compound.

Q. Well, it's not filled with scar tissue in this picture.

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A. No. These -- these are images from the textile that you're taking out of the box; but if you are placing these meshes into the tissues, then you will find as a result this integration into thick scar tissue, making this small pore net a high risk device for -- with a high risk for getting complications.

On the right side you see what is possible, and that is the development that we, together with Ethicon, realized, that we enlarged -- we make the pores much larger, up to 3 to 5 millimeters. And if you place this textile construction into the tissues and then look afterwards what happens, you will find a very flexible, thin mesh tissue compound which is integrated into fat tissue. And, therefore, it is a good example that by reduction of the material to 30 percent of this of the left side by making the pores larger, that you can improve significantly the reaction of their surrounding tissue.

Q. So when you were talking about wanting to have this good tissue, this fat tissue in the pores or the open spaces, in the figure to the right in B, would that be the area where it's the open diamond space?

A. Yes.
Q. That's the area you want the fat tissue to grow?
A. There we want to have this fat tissue, because this fat tissue keeps it flexible, stretchable, elastic.

(Plaintiff's Exhibit No. P1679, PowerPoint presentation entitled "Factors related to mesh shrinkage - What do we know? A review of literature and internal studies", was marked for identification.)

BY MR. ANDERSON:
Q. Okay. I'm going to show you a document, Plaintiff's Exhibit P1679.
Have you seen this document before, Doctor?
A. Yes, I've seen it.
Q. And is it something that you saw in this litigation and it is significant to your opinions in this case?
A. Yes, it is.
Q. Okay. And what is this document, if you would?

A. It's an Ethicon document showing or dealing with the factors related to mesh shrinkage.
Q. If we could just turn over, please, to page 12 of this PowerPoint. And what is the date on the bottom left there?
MR. ANDERSON: If you could blow that up.
BY MR. ANDERSON:
Q. What is the date of this PowerPoint, Doctor?
A. It is done in 2007.
MR. ANDERSON: Okay. Take down the blowup.
BY MR. ANDERSON:
Q. And what do we find from this particular slide?
MR. ANDERSON: And if you would highlight the bullet point 2 from this Ethicon PowerPoint.
THE WITNESS: The people who made this, they acknowledge that the pore size has to be more than 1 millimeter to avoid this fibrotic bridging or this dangerous scarring of the holes.
BY MR. ANDERSON:
Q. Okay. So fibrotic bridging, fibrosis relates to what?
A. Scar.
Q. And bridging relates to what?

A. Bridging means that the scar is filling out completely the pores, the room in between the fibers, which means a risk.
Q. A risk -- what type of risk, Doctor?
A. A risk for contraction of the scar and the mesh and pain and erosion and dysfunction.
Q. As the pore sizes of a mesh in use are greater than 1 millimeter or 1,000 microns, in your opinion will that reduce the risk of contraction?
A. Yes.
Q. And with pore sizes in use that are less than 1,000 microns, or 1 millimeter, in your opinion will that increase the risk of mesh shrinkage or contraction?
A. Definitely, yes.
MR. THOMAS: Just show my objection to leading questions.
BY MR. ANDERSON:
Q. Go ahead.
A. So definitely. A pore size below 1 millimeter will increase the risk for scar bridging and will increase the risk for complications.
Q. Dr. Klinge, I now want to talk about another concept with you, and that's about how and when it is

important to measure the pores of meshes like Prolift. I know that you asked me to bring a basketball net here today to help provide at least a simple explanation to begin with of the importance of the pore measurements; is that correct?
A. Yes.
MR. ANDERSON: Okay. Just for demonstrative purposes and for the record, we have marked the basketball net as Plaintiff's Exhibit P3365.

(Plaintiff's Exhibit No. P3365, Basketball net, was marked for identification.)

MR. ANDERSON: Are you ready? Okay. Thank you.
BY MR. ANDERSON:
Q. So, Doctor, explain what you're trying to show the jury here with regard to pore size and pore measurement.
A. So we know that the pore size is critical for the tissue reaction. We want to have large pores. When you are taking out a net of the box, then the pores may be sufficient; but if you have it in use, if you implanted it and if the surgeon puts some even

slight forces to it, you see that you have this collapse of pores, that even very small pores can get very, very small. And, therefore, by applying these forces to a net, it can make a large pore net to a small pore net and, thereby, increases the risks considerably.

Q. So in your opinion, in terms of patient safety, when is it important to look at the greatest distance between the fibers? Before it goes in the body or after?

MR. THOMAS: Objection.

Q. Or after it's used?

MR. THOMAS: Objection; foundation, expertise designation.

BY MR. ANDERSON:

Q. Go ahead, Doctor.

A. You have to take into account that any force can lead to a pore collapse, and if you want to use a mesh in an area where these forces may occur, then, of course, you have to analyze the pore size in use.

Q. Doctor, did you do testing on the Prolift mesh to determine what would happen to the Prolift pores when stretch forces are applied, for instance, when the Prolift is going to be implanted in a woman?

Did you do testing?

A. We did it.

Q. Please explain just generally the testing that you were involved in regarding looking at the pores after forces are applied to them.

A. In 2005 I met with a colleague of mine from the technical university, Prof. Dr. Thomas Mühl, and we wanted to develop a machine that makes it possible to really measure pore sizes and to really give a measurement what happens to the pores when applying some forces to it. We want to have a measurement that is reproducible, that is objective, and that is reliable. And this has not been done before and, therefore, we developed this machine and finally could finish our work in 2007.

Q. Was that work published in the peer-reviewed literature?

A. Yes. We publish everything and didn't want to restrict it because we -- we want to make it public so that everyone can use this way to optimize his research and development.

Q. And when was that information published in the peer-reviewed literature?

A. We published this, the technique, the

machine, the details of it in 2007, and later on some of the results in 2013.

Q. And do those peer-reviewed publications cover all of the protocols and the test methods and the setup and analysis of the testing?

A. Yes. In every detail.

Q. And did one of those publications actually involve testing of the Prolift device on this machine in order to investigate the pores after stretch is applied?

A. Yes, it is.

Q. And were you involved in the development of the testing and the protocols and parameters for the pore testing for that 2013 article looking at the Prolift mesh?

A. Yes, I was involved in all of this, and I was the medical doctor who was responsible for the interpretation and analysis of this data.

Q. Did the testing that was published by you in 2013 include testing on the Prolift arms?

A. Yes, it did.

(Plaintiff's Exhibit No. PLT0697, Article entitled "Elongation of textile pelvic floor implants

under load is related to complete loss of effective porosity, thereby favoring incorporation in scar plates", was marked for identification.)

BY MR. ANDERSON:

Q. I'm showing you what has been marked as Plaintiff's Exhibit PLT0697. Doctor, is this that 2013 publication regarding your testing of the Prolift device?

A. Yes, it is.

MR. ANDERSON: If you would hit that. Yeah.

BY MR. ANDERSON:

Q. And if you could please go with me to page 5. And we have blown up the left-hand side and have some images as well as the figure box below that.

What are we seeing here, Doctor, in terms of the testing in this scientific research that you did?

A. In the upper part you are just seeing an image of the Gynemesh PS or the Prolift mesh without applying any tension to it. You see the black lines. These are the fibers, and the room in between these are the pores.

Q. And, Doctor, how much force was applied to the Prolift arms that we're seeing in this testing

that was published in 2013?
A. So, yeah, I forgot to explain. The lower image shows the same structure when applying some force to it. So you see the same change as you see with the basketball net. When you apply some forces to it, you find -- you see a collapse of the pores. The pores -- the force that we applied in this experiment was 4.9 newton. That is around one pound.
Q. How did you determine what forces you were going to place on the Prolift arms during this testing that's published in 2013?
A. We had been looking to the many Ethicon internal documents, and we wanted to keep below their limits what they assume to be reasonable limits, and we found two references, at least two references.
Q. And when you're saying references, are you talking about references in the Ethicon documents to the foreseeable amounts of forces that would be placed on the arms during the implantation of the Prolift?
A. Yes.

(Plaintiff's Demonstrative Exhibit No. P3360, PowerPoint slide, a blowup referencing PLT0697,

"Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation in scar plates", was marked for identification.)

BY MR. ANDERSON:
Q. Okay. And we created a slide, I think, to help the jury with that demonstrative, Plaintiff's Exhibit 3360.
MR. ANDERSON: If you could just put in those two references.
BY MR. ANDERSON:
Q. And, Doctor, are these the two references from the Ethicon documents regarding two different estimated forces that may be placed on the arms?
A. Yes. In these two documents you find either 5 pounds in the one document or even 12 pounds in the other, and so we wanted to be below this range, not to show that there is a collapse with extremely high forces, but we want to know what happens to pores when applying just 1 pound.

(Plaintiff's Exhibit No. P0777, Ethicon document, Form for Test Method

Applicability/Suitability, Bates stamped ETH.MESH.01992234 through ETH.MESH.01992237, was marked for identification.)

BY MR. ANDERSON:
Q. I'm showing you, Doctor, what the plaintiffs have marked and is noted on the slide as Plaintiff's 0777, is this the document where they estimated approximately 5 pounds of force?
A. Yes, it is.
Q. And does 2.3 newtons per centimeter estimate to about 5 pounds of force?
A. Yes.

(Plaintiff's Demonstrative Exhibit No. P3357, Document Bates stamped ETH-01755, was marked for identification.)

BY MR. ANDERSON:
Q. Okay. And then showing you what has been marked as Plaintiff's Exhibit P3357, is this the document that you referenced in terms of Ethicon stating that you could estimate 12 pounds of force by the surgeon being placed on the Prolift arms during a

Prolift procedure?
A. Exactly.
Q. Okay. Thank you.
Doctor, what is the significance of your findings with regard to the mesh that we see that has had 1.1 pounds of force applied to it in terms of the tissue response in the patient?
A. It clearly demonstrates and confirms that you have a change of the pore size when applying some force to it and that even very low forces can lead to very, very small pore mesh -- meshes; and, therefore, the application of slight forces changing the appearance of a mesh like this will increase risks.
Q. Okay. Well, put it simply, what does that mesh on the bottom mean to the patient?
MR. THOMAS: Objection; foundation, expertise.
BY MR. ANDERSON:
Q. Yeah. I think we've laid your foundation for expertise. Go ahead, Doctor.
A. The mesh will mean increased risk for scar bridging, shrinkage, contraction, pain, erosion.
Q. Okay. In your review of the internal Ethicon documents in this case, did you determine whether

Ethicon's scientists had considered your and Dr. Mühl's pore testing publications and the effects of mesh pore size under strain?

A. Yes, I did.

(Plaintiff's Exhibit No. P0829, E-mail chain and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.02184130 through ETH.MESH.02184138, was marked for identification.)

BY MR. ANDERSON:

Q. Let's pull up the two documents so the jury can see what we're talking about.

I'm handing you what has been premarked as Plaintiff's Exhibit P0829. Have you seen this document before, Dr. Klinge?

A. Yes, I've seen.

Q. Is this something you considered and reviewed in arriving at your opinions in this case?

A. Yes.

MR. ANDERSON: If we could blow up the top part of this and also show the attachment that goes with this article -- with this internal

Ethicon e-mail. Yes.

BY MR. ANDERSON:

Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment.

MR. THOMAS: Objection; calls for Ethicon's state of mind.

THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it.

(Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.)

BY MR. ANDERSON:

Q. Okay. Let me show you another document which is Plaintiff's Exhibit 1437, which is another e-mail, an Ethicon e-mail, this one dated 2010, from a Dr. Joerg Holste to a Dr. Juergen Trzewik. Do you know Dr. Joerg Holste?

A. Yes, I know. He is a leading scientist in

Hamburg, Ethicon.

Q. Did you work with him in the last 20 years?

A. He was a member of the working group that has been working together with us.

Q. And if we see the attachment to this e-mail, two years later what do you find here, Doctor?

MR. THOMAS: Objection; postdates Ms. Bellew's surgery, and there is nothing here to comment on other than the fact it's just a transmittal letter.

BY MR. ANDERSON:

Q. Go ahead, Doctor.

A. In 2010 they again circulated it to the members of their research groups.

(Plaintiff's Exhibit No. P1087, PowerPoint presentation entitled "Thunder: Technical Review, Somerville 28th February 2008", was marked for identification.)

BY MR. ANDERSON:

Q. I'm showing you what has been marked as Plaintiff's Exhibit P1087.

Have you seen this document before,

Dr. Klinge?

A. Yes, I've seen it.

Q. And is it significant to your opinions in this case today?

A. Yes, it is.

Q. And what generally is this document?

A. It's a technical review from Ethicon.

Q. And what year is this dated?

A. It's made from 2008.

Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before?

A. Yes, I've seen it.

Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury?

A. Yeah.

Q. Okay. What do you see here, Doctor, that you would like to point out to the jury?

MR. ANDERSON: Highlight 4.

A. So in this definition of the requirements to improve, as it is said in the subtitle, "Improving lives by advancing the standard of care in tissue repair," they identify it as an important point to

improve this -- these results, shrinkage and stiffening; and they defined a pore size of more than 3 millimeter as being essential, and for the first time they mentioned a pore size of 1 millimeter under stretch. So they acknowledged that you have to look to the pore size and use additionally to the pore size in the box or without any forces.

MR. THOMAS: Objection; move to strike. Goes beyond what the document says.

BY MR. ANDERSON:

Q. I want to go back to a document previously used, which was Plaintiff's Exhibit 1156. We looked at this with the jury a little earlier today, and --

MR. THOMAS: Can you give me just a second, please?

MR. ANDERSON: Sure.

MR. THOMAS: Thank you. I have it now.

BY MR. ANDERSON:

Q. Okay. If you go to page 13 of this 2008 Ethicon PowerPoint, have you seen this slide before, Doctor?

A. Yes, I've seen it.

Q. And is that significant to your opinions in this case?

A. Yes.

MR. ANDERSON: Okay. Highlight the left-hand side of this picture.

BY MR. ANDERSON:

Q. What are we seeing here, Doctor?

A. So in this image you see the same phenomenon as we have seen in -- with the basketball net, that when applying some forces, the pores collapse and you will create a small pore mesh.

Q. We see the word "effective porosity" there. What's that refer to?

A. Effective porosity, that's exactly the term that we were able to define with the testing that we do a lot of, Professor Mühl. So they adopted this terminology in --

Q. Just explain that real simply for the jury, what effective pores would be.

A. So effective pores means that is the area of the good pores roughly. So the good pores are those with fat. If you start with half of the pores are filled by fat in the upper line, then it's going to zero in the lower if you applied some force to it. So you only have small pores, noneffective, poor pores, risky pores in the lower part when you apply the force to it.

Q. Thank you, Doctor.

(Plaintiff's Exhibit No. P2995, PowerPoint presentation entitled "Mesh Properties - How important are they?" was marked for identification.)

BY MR. ANDERSON:

Q. Going -- I want to show you now Plaintiff's Exhibit P2995. Is this a document that you have reviewed and relied upon in this litigation?

A. Yes, I did.

Q. And what is this, Doctor?

A. This is a PowerPoint presentation from Ethicon.

Q. And if we would go to slide 25 of this presentation by Ethicon.

A. Yes.

Q. Is that significant to your opinions that you're offering here regarding pore size and pore deformation after stretch is applied?

A. Yes, it is.

Q. Okay. Please explain for the jury.

A. Because this figure wants to express in the

title already that large pores become very small under stress, and it was in contrast to the previous one, which was a drawing. It shows that was an Ethicon experiment showing or trying to demonstrate what happens to the textile structure to the pores when applying a force to it.

Q. As part of your review of the materials in this case, did you see the Ethicon video of a Prolift anterior actually being implanted in a woman?

A. Yes, I did.

Q. And is that video significant to your opinions in this case?

A. Yes, it is.

Q. Okay. I don't want to have to show the jury the entire video because they may have already seen it, but did you ask me to create some screenshots from that video?

A. Yes.

Q. Okay. And did we create a slide showing these videos --

A. Yes.

Q. -- these screenshots for the jury?

A. Sorry.

Q. Sorry. Yes?

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A. Yes.

(Plaintiff's Demonstrative Exhibit No. P3361, PowerPoint slide entitled "Pores Collapse Under Tension," referencing P2995, ETH.MESH.05237872, PLT 0697, P1452 - ETH.MESH.000007, was marked for identification.)

BY MR. ANDERSON:

Q. Okay. I'll put up this next slide which we'll use for demonstrative as P3361. Just one second. Go ahead.

MR. THOMAS: Before you show that to the jury, are you representing that this is Ms. Bellew's surgery?

MR. ANDERSON: If I did, I would have said that.

MR. THOMAS: That's why I show my objection to this not being representative of Ms. Bellew's surgery.

MR. ANDERSON: It's okay. It's your document.

BY MR. ANDERSON:

Q. So showing you Plaintiff's Exhibit P3361,

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over to the right is that a screen shot from a DVD produced by Ethicon of Ethicon surgeons implanting a Prolift anterior into a woman?

A. Yes.

Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why do you think that's important for the jury to see, Doctor?

A. Because it makes very clear that we have to deal with a realistic problem. On the left you see the image from the Ethicon study where they just described it.

In the middle you see an image of our testing where we tried to measure it to quantify the consequences to different forces.

And on the right you see exactly the same deformation, the same roping of the arms during the OR. So the collapse of pores is a real phenomenon.

Q. So whether we can take the Ethicon document that says 5 pounds of force is placed by the surgeon on the arms during implant or 12 pounds of force during implant, this image to the right, is this the resulting characterization of the mesh arm after either 5 or 12 pounds of force are placed on it?

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A. Obviously the forces in the OR when in use are too high for this specific design of this mesh, leading to this roping, even in this teaching video.

MR. THOMAS: Objection; move to strike, beyond the area of expertise and not a disclosed opinion.

MR. ANDERSON: It certainly was disclosed opinions, and the videos are in his reliance materials. And he talked about initial force, 12 pounds of force. He talks about 5 pounds of force. He says that when you use the applied loads that Ethicon used that you get to see pore deformation. He said that you see it from Ethicon's documents, his documents and the DVD.

BY MR. ANDERSON:

Q. Okay. So if we can just zoom in on this Ethicon DVD on the right-hand side produced by Ethicon in this litigation, is that significant to your opinions? Is that what you were discussing with the jury of how the mesh is curled and roped and deformed?

A. Yes.

MR. THOMAS: Same objection.

THE WITNESS: Exactly. So this is not longer

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any large pore mesh design. This rope will be integrated into dense scar tissue and nothing -- nothing else, and it will become stiff and rigid.

BY MR. ANDERSON:

Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the Ethicon box?

A. No, definitely not.

MR. ANDERSON: Okay. You can take that down. Oh, actually, bring that back up.

BY MR. ANDERSON:

Q. Do you have an opinion to a reasonable degree of medical and scientific certainty as to whether the mesh arms that the jury is seeing in the right-hand picture would result in unnecessary risk to the tissues?

MR. THOMAS: Objection; beyond his area of expertise.

THE WITNESS: The appearance of such a mesh in this roping form means a considerable risk, and because it is -- there is no need for this, it is an unnecessary risk.

BY MR. ANDERSON:

Q. And would that unnecessary risk involving the

tissue response, would that risk be the same with mesh of this appearance whether it was in the abdominal tissue, the pelvic tissue or the tissue under your armpit?

MR. THOMAS: Same objection.

THE WITNESS: A mesh curled like this, getting these small pores like this one will result everywhere in the body in a scar mesh compound that is stiff and rigid and not flexible any longer.

MR. ANDERSON: You can take that down.

BY MR. ANDERSON:

Q. After your review of all the materials in this case regarding Ethicon's meshes for treating pelvic organ prolapse, all of your work that you've done in the scientific literature, conferences you've spoken at around the world, the conferences you've spoken as an invited lecture by Ethicon, and your work as a hernia surgeon both implanting and explanting polypropylene meshes, your work in reviewing thousands of hernia mesh explants from humans, your review of looking at explants from pelvic floor -- from the pelvic floor in women, do you have an opinion to a reasonable degree of medical

and scientific certainty as to whether the Prolift was a safe design or an unsafe defective design?

MR. THOMAS: Objection.

A. I have --

MR. THOMAS: Excuse me. Just let me base my objection to the foundation that he's laid. Go ahead.

BY MR. ANDERSON:

Q. Do you?

A. I have.

Q. Okay. And what is that opinion, Dr. Klinge?

A. The Prolift carries unnecessary risk and, therefore, it's unsafe.

Q. Doctor, did we prepare a slide for the jury regarding your opinions of what you consider to be the critical design defects in the Prolift?

A. Yes.

- - -

(Plaintiff's Demonstrative Exhibit No. P3362, PowerPoint slide entitled "Prolift Unsafe/Defective Mesh Design", was marked for identification.)

- - -

MR. ANDERSON: Okay. If we could show that. That is Plaintiff's Demonstrative 3362.

BY MR. ANDERSON:

Q. Is this the PowerPoint that you wanted me to prepare, Doctor?

A. Yes.

Q. Okay. You have a point there, "Less Material = Safer," under the heading "Prolift Unsafe/Defective Mesh Design." What do you mean by this first bullet point?

A. It became clear from all our work that less material would reduce the risk of inflammation and scarring, so less material will make it safer and there is no need for this amount of material as it is used for the Prolift.

Q. Okay. Let's go to your next point.

A. From all our work, it is evident and clear and undoubted that large pore -- larger pores will make it safer. They will help that the pores are filled by fat tissue, keeping it flexible. So, therefore, larger pores would make it safer, and there is no need for the small pores of the Prolift.

Q. And your third point?

A. The pores have to resist a collapse when applied, some forces that we have seen that these forces have been applied. And, therefore, a mesh

design that avoids this collapse under forces would be much safer, and there is no need that you bring in a mesh that shows this roping. There is no need, and, therefore, all these three points are unnecessary risks.

Q. After all of your review of the thousands of pages of depositions, the internal Ethicon documents, all the things that we've been just covered throughout your testimony today as well as your work with Ethicon as a consultant for ten years and over 20 years of work in the field, do you have an opinion to a reasonable degree of medical and scientific certainty as to whether the Prolift was safely designed to be permanently implanted in a woman's pelvis?

A. Yes.

MR. THOMAS: Objection; foundation, expertise.

BY MR. ANDERSON:

Q. Now answer the question.

A. Yes.

Q. And what is that opinion, Doctor?

MR. THOMAS: Same objection.

BY MR. ANDERSON:

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Q. Now go.
A. Because it carries unnecessary risk. It is designed unsafe and defective.
MR. ANDERSON: Thank you. No further questions at this time.
THE VIDEOGRAPHER: We are off the record. The time is 10:22 a.m.
(A recess was taken from 10:22 a.m. until 10:33 a.m.)
THE VIDEOGRAPHER: This marks beginning of Video Number 2. We are back on the record. The time is 10:33 a.m.
CROSS-EXAMINATION
BY MR. THOMAS:
Q. Good morning, Dr. Klinge.
A. Good morning.
Q. You're an expert that's been retained by Mr. Anderson in this case; is that correct? Expert witness?
A. Yes.
Q. And you're paid for the time that you spend working on this matter?
A. Yes.
Q. And you're paid at the rate of $500 an hour; is that right?

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A. Yes.
Q. How much money have you been paid to work on this case?
MR. ANDERSON: Objection. You mean Bellew?
MR. THOMAS: Yes.
MR. ANDERSON: The Bellew case.
THE WITNESS: It's about $20,000, included the tax. In Germany you have to reduce it almost by half.
BY MR. THOMAS:
Q. Okay. And in preparation for your deposition today, you met with Mr. Anderson?
A. Yes.
Q. And how many days did you meet with Mr. Anderson?
A. Three days.
Q. Okay. And how many hours did you spend with Mr. Anderson in preparation for your deposition?
A. Six hours a day.
Q. So about 18 hours?
A. Maybe.
Q. So about $9,000; correct?
A. Yeah.
Q. All right. Now, from the mid-1990s to 2006,

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you were a practicing surgeon with a focus on abdominal hernia repairs; correct?
A. No. Ah.
Q. What?
A. Yeah. So I just understand. I was an abdominal surgeon with the focus on hernia surgery. That is okay, yeah.
Q. Okay. Fine. Thank you.
And I'm not trying to trick you. If you don't understand my question, let me know, and I'll try to rephrase it. I know that English is not your first language, and I'll do the first I can.
A. And I am not sure every time.
Q. And I speak West Virginian. I don't speak German.
Doctor, you've not performed surgery since 2006, have you?
A. Not in humans.
Q. Okay. And prior to 2006, you treated hernias?
A. Yes.
Q. And a hernia is essentially an organ pushing through the abdominal wall; correct?
A. Not always.

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Q. Why can you not describe a hernia as an organ pushing through the abdominal wall?
A. Because there are hernias, for example, close to the esophagus, through the diaphragm, where you have a hernia, but it is not a defect in the abdominal wall.
Q. Okay. Well, you could repair hernias with sutures; is that correct?
A. You can try to repair it by sutures, yes.
Q. And sutures are sometimes called stitches?
A. Yes.
Q. And sutures and stitches are the Prolene that you showed to the jury on direct examination; correct?
A. There are many kind of different sutures, different suture materials, and one of the suture material is Prolene.
Q. And when you repair a hernia with sutures, you basically put the tissue back in place and then support it with the stitches; correct?
A. The stitches are supported to keep the approximation of the tissues together, yeah.
Q. Okay. And you can also treat hernias with surgical mesh; correct?

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A. Yes.
Q. And you can repair hernias with polypropylene mesh; correct?
A. Yes.
Q. There are about 20 million surgical mesh implantations every year; true?
A. That is said by Saunders in his reference. Whether it's true, I didn't count it.
Q. And abdominal hernia repair is the most frequently performed operation and surgery; correct?
A. That is correct.
Q. And the use of mesh to repair hernias is an important option for patients; true?
A. Yes.
Q. Polypropylene is the most widely used mesh for hernia repair; true?
A. That should be true.
Q. And mesh implants made of polypropylene have been used in the human body since 1963; true?
A. That is true.
Q. And Ethicon began selling Prolene mesh for hernia repair in 1974?
A. Yeah.
Q. And the Prolene mesh that's used to repair

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hernias is the same material that is used to make Prolene soft in the Prolift; correct?
A. Please, can you --
Q. Prolene mesh used in hernia repair is made of the same polypropylene material that is used to make Prolene soft for use in the Prolift?
A. I think so, yeah.
Q. Now, you started implanting polypropylene mesh for hernia repair in the early 1990s; true?
A. Yes.
Q. And you performed about 200 hernia repairs using mesh; correct?
A. Yes.
Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct?
A. Yes.
Q. Well, just so it's clear, you never implant polypropylene in that form into a body, do you?
A. No.
Q. The polypropylene is woven or knitted into a mesh so it can be implanted; correct?
A. Yes.

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Q. And we don't have a Prolift here, but the Prolift itself does not look like Exhibit 3364; correct?
A. Yes.
Q. Now, the hernia meshes that you used to repair hernias are often bigger than the meshes used in the pelvic floor to repair a pelvic organ prolapse; correct?
A. The meshes can be bigger, but the area for implantation is completely different.
Q. So are you telling the jury that implanting a mesh in the abdominal area is different from implanting a mesh in the pelvic floor?
MR. ANDERSON: Objection.
THE WITNESS: Yes.
MR. ANDERSON: Go ahead.
BY MR. THOMAS:
Q. Stay with me, though, for a minute. But the amount of mesh that you implant in the abdominal area to repair hernias is often much more than the amount of mesh that's used in this anterior Prolift that you have described in P3364; correct?
A. It was correct before we developed together with Ethicon these large pore meshes, which have a

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reduced amount of material. We could reduce the amount of polypropylene to 30 percent of these heavyweight small pore meshes, and, therefore, it is difficult. It depends from -- from the specific size of the mesh. Then you can do this calculation and look whether it exactly fits or whether it's a little bit more.
Q. Meshes that you used before 2006 to implant into humans for the repair of hernias had more polypropylene in them than the polypropylene that you showed the jury in 3364; correct?
A. 2006 you said?
Q. Before 2006. You implanted meshes --
A. We --
Q. -- some meshes that had more polypropylene than is present in 3364.
A. After our development of Vypro of these large pore meshes with Ethicon, we only use these material-reduced methods; and, therefore, the use of this huge amount of material was very, very rare.
Q. You know today that mesh is used in the repair of hernias by a doctor every single day, in Germany, in the United States, everywhere around the world that has more mesh than is present in 3364,

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don't you?
A. I know that in Germany 90 percent -- more than 90 percent of the meshes used for hernia repair are large pore meshes.
Q. And what meshes are those specifically?
A. These are Ultrapro. Ultrapro is the leading from Ethicon.
Q. Okay. Are you saying Ultrapro is appropriate for the pelvic floor?
A. No.
Q. So just so your testimony is clear, it's not your opinion that Ultrapro is an appropriate mesh to treat pelvic organ prolapse in the pelvic floor; true?
A. If you stick to the third point we presented there, that it has to prevent a pore collapse -- and Ultrapro obviously does not prevent a pore collapse when applied to forces; therefore, it is not the best idea to use Ultrapro in this -- for this indication, yes.
Q. It's true that you do not have the opinion that Ultrapro is a reasonable alternative design for the use of mesh in the treatment of pelvic organ prolapse; true?

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MR. ANDERSON: Objection to form.
THE WITNESS: As it carries unnecessary risk, I am sure that it is not a safe alternative.
BY MR. THOMAS:
Q. Okay. Now, when you started implanting mesh for hernia repair, you didn't understand all of the biomechanical demands of the abdomen; true?
A. It is a permanent learning that I have when I started surgery. I don't know, but I permanently learned about it. And we learned a lot about these meshes, and, of course, when we started to make this research, we didn't know everything.
Q. Are you able to answer my question yes or no? Let me ask it again.
When you started implanting mesh for hernia repair, you didn't understand all of the biomechanical demands of the abdomen; true?
A. What do you think of "all"?
Q. Doctor, let me hand you your deposition that you gave.
I'm sorry. It's the wrong one.
No. I was right.
MR. ANDERSON: Thank you, Counsel.
BY MR. THOMAS:

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Q. Turn to page 89 of the deposition, please.
MR. ANDERSON: I think you gave me two copies, Counsel. Yeah. You gave me --
MR. THOMAS: I think there's two days.
MR. ANDERSON: Oh, you're going to need both.
THE WITNESS: 98?
BY MR. THOMAS:
Q. Page 89, line 16. You there?
"QUESTION: And, Doctor, in the early '90s the physicians didn't understand all of the biomechanical demands of the abdomen; is that correct?
"ANSWER: There was limited knowledge about the biomechanics of the abdomen."
Did I read that correctly?
MR. ANDERSON: Excuse me. I will object. That is not the same question you asked. You asked, "Do you know everything," and here you changed the question from this to what it was in the deposition. So if we were at sidebar, I would have pointed that out to the judge.
MR. THOMAS: And I understand your objection.
BY MR. THOMAS:
Q. Did I read that correctly?

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A. Yeah.
Q. Okay.
MR. ANDERSON: It's an inappropriate use of the deposition, so that's my objection.
MR. THOMAS: And you stated it clearly.
BY MR. THOMAS:
Q. And, Doctor, it's clear that in the '90s physicians didn't understand all of the biomechanical demands of the abdomen; true?
A. There was limited knowledge about the biomechanics of the abdomen. Still open questions.
Q. Okay. And when you were performing hernia surgery, it was important for you that the patient understand whether the benefits of that hernia surgery outweighed the risks of that hernia surgery; correct?
A. That is correct.
Q. And it's your job as a doctor to explain the risks of hernia surgery to the patient so the patient can make that informed decision; correct?
A. Yes.
Q. And it's true, Doctor, that any surgery has risks?
A. Which type of risks do you think?

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Q. Well, is it true that every hernia surgery has risks?
A. Has some risks.
Q. And it's your job to tell a patient about those risks so that they can make a decision about whether to have the surgery; correct?
A. I have to tell him not that there are possible ways to get some complication, but I have to give him the information that he gets a good estimate how big the risk is, whether there is an alternative with a less risk and what is the benefit.
Q. And --
A. So is it a necessary risk or is it an unnecessary risk? And all this together I have to discuss with the patient. It is not so simple to say there are some risks.
Q. And you tell the patient that there is a lifelong risk of infection from that mesh implant, wouldn't you?
A. From the moment we know there is a -- that we learn that there was this permanent inflammation that you have a lifelong risk for infection. You have an implant. They received an implant. It's not a tissue repair. They received a plastic implant for

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the rest of their lives.
Q. And anytime you have a plastic implant, there's a risk, a lifelong risk of an infection; true?
A. Yes.
Q. And that would be for a hip or for a knee just as well as a mesh; correct?
A. But the numbers are different, and it is different to treat it.
Q. Answer to my -- Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no.
MR. ANDERSON: Objection; beyond the scope of cross -- beyond the scope of direct.
THE WITNESS: If you are thinking of the principal possibility of a lifelong risk to get an infection, yes.
BY MR. THOMAS:
Q. Thank you.
And when you're talking to a patient about the risks of hernia repair, you talk to a patient about the risk of a late onset of chronic pain; correct?

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A. This topic surely is mentioned with the patient, that chronic pain may be a serious complication after operation, yes.
Q. And when you say late onset, that means that this pain does not manifest itself until after the surgery sometime; correct?
A. Yes.
Q. And you also tell patients that hernia mesh is difficult to remove; true?
A. Yes.
Q. And you talk to a patient about a risk of hernia recurrence?
A. Yes.
Q. And a hernia recurrence means that the mesh repair did not work and the hernia repair comes back; correct -- excuse me, the hernia comes back; is that correct?
A. There are different definitions of recurrence, and where the hernia comes back, whether it's really a problem that the mesh doesn't work, whether it's a new hernia that is for the patient a recurrence. So it is not so simple, but we are discussing the manifestation of another hernia despite using a mesh.

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Q. And a patient needs to know that there's a risk that the surgery won't work; correct?
A. Yes.
Q. And you talk to a patient who is looking at a potential hernia repair with mesh about the risk of mesh shrinkage; correct?
A. Yes.
Q. And any mesh will have a shrinkage or contracture rate of at least 20 percent; correct?
A. At least 20 percent? The difference is the extent of this one.
Q. Any -- any mesh -- it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct?
A. There may be some conditions where it's a little bit lower, but, yeah, sure, more or less it is. You have to assume a contraction of 20 percent.
Q. And when you were treating patients for hernia repairs, you explained all of these risks to the patient so the patient would understand?
A. But in a completely different way.
Q. Is that true?
A. I explained these risks to the patients.
Q. So when you used polypropylene mesh for

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hernia repair, you believed that the benefits of that mesh outweighed any risks to your patient; true?
A. In some specific patients in some specific conditions where we are discussing the alternatives, we are discussing the risks of the patient's conditions, the risk of the procedure, the risk of the biomaterials, all this together will end up in the risk-benefit ratio. And when you have all this information, how often something occurs, then you can discuss it with the patient and you can make your decision, yes.
Q. Well, when you recommended mesh to a patient for the repair of their hernia, you believed that the mesh that you were going to use, the benefits of that mesh outweighed the risk to the patients; true?
A. In those patients where I am using meshes, I have been using meshes, the decision of me and the patient was that in this case the use of a specific mesh in a specific way outweighs the risks.
Q. Okay. Now, over the last 20 years, there are millions of people on earth walking around with mesh in their body, and a large percentage of those meshes are either polypropylene or they contain polypropylene; true?

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A. Sure.
Q. Yeah. Now, you've never treated the plaintiff in this case; correct?
A. That is correct.
Q. And you've never examined the plaintiff in this case; correct?
A. That is correct.
Q. And you have never rendered any medical diagnosis specific to the plaintiff in this case; correct?
A. That is correct.
Q. And you have never examined the actual mesh explanted from the plaintiff in this case; correct? Other than the photograph you looked at?
A. I think so, yeah.
Q. Now, I want to look at that photograph that Mr. Anderson showed you. Do you have it in front of you? Exhibit P3356.
Do you have that, Dr. Klinge?
A. Yes.
Q. Now --
A. I see.
Q. In the top left-hand corner -- you understand this to be a mesh explant from Mrs. Bellew?

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A. Yes.
Q. And the top left-hand corner, is that the area of mesh that you were describing in your direct examination?
A. Yes.
Q. And that mesh has -- is covered with tissue; correct?
A. Yes.
Q. And that mesh has been stored in formaldehyde; correct?
A. Yes.
Q. And you have not measured that mesh to determine the extent to which any pores in that mesh have collapsed, have you?
A. Not specifically this mesh.
Q. Thank you.
As a matter of fact, you have not performed any analysis on the mesh specific to Ms. Bellew; correct?
A. Specifically, yeah.
Q. Now, you have not ever performed surgery for the repair of pelvic organ prolapse; correct?
A. That is correct.
Q. And we talked about the Prolift before.

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You've never used a Prolift in any surgery; correct?
A. That is correct.
Q. And do you know the tools that are used to place Prolift?
A. I've seen it on the video.
Q. There's a trocar?
A. Yes.
Q. And there's a cannula; correct?
A. Yes.
Q. You've never placed a mesh with trocars, have you?
A. No.
Q. You've never placed a mesh with cannulas, have you?
A. No.
Q. You've never placed a mesh using the same tools as Prolift; correct?
A. That is correct.
Q. Now, you were shown Exhibit 3361. Could you get that in front of you, please.
MR. THOMAS: Could you pull that up, please, 3361, so the jury can see it?
BY MR. THOMAS:
Q. And this is the slide that you talked about

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on direct examination, and this is a surgical procedure involving the Prolift; correct?
A. Yes.
Q. And it uses cannulas; correct?
A. Yes.
Q. And it uses trocars; correct?
A. Yes.
Q. And you've never used either one of those; correct?
A. Yes.
Q. And you understand that the mesh is to be placed tension-free inside the body; correct?
A. What do you mean by is said or --
Q. Do you know that -- do you know that a surgeon is to place the Prolift in the body tension-free? Do you know that?
A. There are some ideas that it should be done tension-free, but obviously it is not possible to place it tension-free; therefore, there is no measurement that it is done tension-free. There is -- it's not a fact.
Q. But you have not done one; correct?
A. Yes.
Q. It's correct that you have not done one?

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A. It is correct that I never did it.
Q. Okay. You've never tried to place mesh tension-free inside a woman; correct?
A. I -- the abdominal wall surgery, the use of meshes, is supposed to be in a tension-free area. We know that's -- and I did it in woman.
Q. Okay. But not in a pelvic floor?
A. Not in the pelvic floor.
Q. Okay. And when the Prolift is placed, it goes through cannulas; correct?
A. Yes.
Q. And that allows for the smooth passage of the mesh through the cannulas; correct?
A. It is supposed that you need some forces, according to the internal documents from Ethicon. It is supposed that you need some forces to do so.
Q. And you don't know what this mesh looks like inside of the person on whom this surgery is being performed, do you?
A. In the video you have it -- a view from inside, and it appears -- though the quality is not very good for these slides, but it appears as if these -- this mesh in the video is looking curled even inside; and from all the explants that we were

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able to investigate, we saw this deformation, this roping in all of these explants, wherever they were taken. It's not a phenomenon that is outside the body. It's inside the body.
Q. You've not seen it yourself, have you, Doctor?
A. In this case, not.
Q. Okay.
A. Only in the video I've seen it.
Q. And the only video that you've seen of a Prolift repair is the one that you just discussed; correct?
A. That is a video made by Ethicon --
Q. Okay.
A. -- as a teaching video.
Q. And you don't have any basis to give an opinion as to what the mesh looks like in the body, do you?
MR. ANDERSON: Objection.
THE WITNESS: If you --
BY MR. THOMAS:
Q. Is that yes or no? You can tell me yes or no and then tell me what it is.
A. Please then.

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Q. Do you have any basis to understand what the mesh looks like in the body after it's implanted?
A. I have a basis, yes.
Q. And what is that?
A. This basis is our explants, our -- the visualization of many operations that have been shown on the conference where you see it that is the appearance of the arms for Prolift total, Prolift posterior. When you're looking to all of these teaching videos, you always will see that the mesh is not longer laying there in a flat way, but they showed this roping. You can find it almost every -- in every video and every transmission of an operation.
Q. On the outside?
A. No. Before -- sometimes you are able to see the arms before closing all wounds, or sometimes you may make some laparoscopy looking from inside.
Q. Now, you're not an expert in pelvic floor surgery with regards to the surgical procedure used to treat pelvic organ prolapse; true?
A. In regard to surgical procedure, it's true.
Q. And you're not a specialist for finding the best indication for a mesh in the pelvic floor; true?

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A. That is true.
Q. And you've never consulted with Ethicon on issues of pelvic organ prolapse; true?
A. That is true.
Q. Now, you're not an obstetrician; true?
A. Please, what?
Q. You're not an obstetrician?
A. What is an obste --
Q. Baby doctor.
A. No, I'm not a baby doctor.
Q. You're not an obstetrician?
A. Okay. Yeah. Yeah.
Q. You're not a gynecologist?
A. I'm not.
Q. You're not a urologist?
A. I'm not.
Q. And you're not a urogynecologist; correct?
A. I'm not.
Q. And you've never completed a fellowship or residency in those fields; correct?
A. That is correct.
Q. And you have never studied the pelvic forces -- pelvic floor forces in a human; correct?
A. We tried. We tried in some research projects

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to define the -- or to learn about the anatomy and the forces.
Q. But you -- did you ever complete the study of pelvic forces in the human?
A. We completed some of the studies, and I guess some of this already has been published in a peer-reviewed literature, but of course we are not finished with all our studies in this field.
Q. Let me show you another transcript of testimony, please, and direct your attention to page 3497.
A. 47?
Q. 3497, line 15.
A. 3497.
MR. ANDERSON: And I'll just place an objection on the record. This is outside the scope of direct. Didn't talk about pelvic forces.
What's your page?
MR. THOMAS: 3497.
BY MR. THOMAS:
Q. Do you have it, Doctor?
A. Yes.
Q. Line 15.

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"QUESTION: You've not studied the pelvic floor forces in a human; correct?
"ANSWER: That is correct."
Did I read that correctly?
A. Yes.
Q. Thank you.
Now, you agree that mesh is an important option for patients in pelvic floor repair; correct?
A. In some patients, yes.
Q. And you agree that polypropylene is an appropriate use in pelvic floor if you have the right construction of that polypropylene; correct?
A. If it's a right construction for this specific purpose, yeah, it can be.
Q. Okay. And 91 percent of all gynecological nonabsorbable meshes are polypropylene; correct?
A. It should be, correct. We never -- I never analyzed or counted it.
Q. Now, over the years you talked about your work from Ethicon. Ethicon paid you for your work, didn't they?
A. In the years from 2000 to 2005, yes. In the years before, no.
Q. And you received royalties from Ethicon for

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sales of Vypro; correct?
A. In these -- this is the payment you're talking of. This is in the years from 2000 until 2005. I got something like royalties for the selling of Vypro and Ultrapro.
Q. And so every time Ethicon sold a Vypro and an Ultrapro, you earned money; correct?
A. Yes.
Q. You earned about 20,000€ a year from royalties from Ethicon from 2000 to 2005; is that correct?
A. That is correct.
Q. Now, you received no royalties for the sales of Prolene mesh; correct? Prolene Soft Mesh.
A. Yes.
Q. I want to go back to another exhibit that you talked about on direct, and it's Plaintiff's Exhibit 0697. Do you have that?
A. Not yet.
Q. 0697 is your 2013 study.
Do you have that now?
A. Yes.
Q. And Plaintiff's Exhibit 0697 was published in 2013?

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A. Yes.
Q. Now, in this study in 2013, you compare Prolift and Prolift+M with DynaMesh; correct?
A. That is correct.
Q. And you and Mr. Mühl tested this -- these meshes on the same machine that you conducted your test back in 2007; correct?
A. Yes.
Q. And the machine that you developed in 2007 was fabricated in part by a company known as FEG; correct?
A. Please, can you -- can you please repeat it.
MR. THOMAS: Can you read that back, please.
THE COURT REPORTER: "And the machine that you developed in 2007 was fabricated in part by a company known as FEG; correct?"
THE WITNESS: I don't think they fabricated any part of this machine.
BY MR. THOMAS:
Q. And what do you base that on?
A. Because the FEG makes meshes and doesn't make any computer hardware, photograph, image maker, so nothing -- no component of this machine can be done by the FEG.

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Q. Okay.
A. So I think they -- Professor Mühl bought it from -- or has made it from their own engineers from the university.
Q. Okay. Have you read the depositions of Professor Mühl?
A. I guess I have, yeah.
Q. Okay. Did you recall any testimony he gave in that regard?
A. No.
Q. All right. When you did your testing back in 2005 to 2007 and you developed this machine, did you do it in conjunction with the FEG?
A. Yes. It was a -- it was a funded project by the ministry together with the FEG and Professor Mühl, yeah.
Q. And the FEG manufactures meshes?
A. Yes.
Q. And the FEG makes PVDF meshes; correct?
A. Yes.
Q. And PVDF meshes are the meshes that you compare -- used to compare the other meshes in the study; correct?
A. We made a comparison between this specific

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Gynemesh PS from polypropylene to a DynaMesh made of PVDF in this specific -- two specific meshes.
Q. And just so the jury understands, DynaMesh is manufactured by FEG; correct?
A. Yes.
Q. And you, at the time of this study, were a paid consultant for FEG; correct?
A. Yes.
Q. Now, in the first paragraph of this study -- excuse me, in the abstract in this study, you note on the right side --
MR. THOMAS: Can you bring that up, please? It's 0697.
MR. KAUFFMANN: Which page?
MR. THOMAS: Front page. Excuse me. Let's go to page -- the third page of that article. Under Prolift+M system Gynemesh and Ultrapro, first sentence.
BY MR. THOMAS:
Q. "Without any strain, the effective porosity was 57.5 percent, and the majority of pores had a diameter of larger than 100 microns" -- "1,000 microns."
Correct?

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A. Prolift+M, yeah. Yeah. You read it correctly.
Q. Okay. And back on the first page in the abstract on the right side, you identify the fact that Prolift in tension-free can be considered a large pore Class I mesh; correct?
A. Yes. It's one of bigger -- it has one of the biggest pores of all mesh available.
Q. And down at the bottom you say that both meshes -- this is on the right side of the first page.
"Both meshes can be classified as large pore Class I mesh with an effective porosity that is sufficient to prevent bridging of scar tissue throughout the entire pore."
Correct?
A. I didn't -- didn't -- couldn't follow where you have been reading.
Q. I'm down --
MR. ANDERSON: You changed. He was down in the abstract. You're moving down.
BY MR. THOMAS:
Q. Down on the right side, about two-thirds of the way on the right. "The Gynemesh PS is identical

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to the Prolene Soft Mesh for hernia repair, and the textile structure of the Prolift+M system is copied from the Ultrapro hernia mesh."

A. Is identical, yes.

Q. "Both meshes can be classified as large pore Class I mesh with an effective porosity that is sufficient to prevent bridging of scar tissue throughout the entire pore."

That's true?

A. You read -- no, that's not true, but you read it correctly. It's not true if you applied some forces to it.

Q. Okay. Well, this --

A. This is just restricted to the situation where you don't apply any forces.

Q. Okay. And it's only if you apply forces to it that, as far as you're concerned, it loses the adequate pore size to prevent against this bridging; correct?

A. Then, yes, it's correct that this mesh then change to a small pore, dangerous high risk device.

Q. All right. Now, the testing that you have in Exhibit 0697, you were retained as a plaintiff's expert at this time; correct?

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A. I did not understand this.

Q. You were a plaintiff's -- you were an expert for Mr. Anderson at the time you did the work on this paper; correct?

A. Yes.

Q. And you were paid for your time in connection with this work; correct?

A. Yes.

Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation against Ethicon at the time that you did this study; correct?

A. Yes.

Q. And it's also correct that you didn't disclose in this study that you were a consultant for the FEG; correct?

A. Yes.

Q. And it's also correct that you show in this article that the -- or purport to show that the DynaMesh retains a better effective porosity than the Ethicon mesh under strain; correct?

A. We showed that there is an option to do it without collapse of the pores, and this is done by the DynaMesh. That was shown in the article.

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Q. Where is your basketball net?

A. We don't have ball.

Q. Don't need a ball.

A. Okay.

MR. ANDERSON: Would you like to use my net, Dave?

MR. THOMAS: I would, please.

BY MR. THOMAS:

Q. I don't remember what number we attached to this net, but I want to ask you some questions about the net.

You used the net to describe to the jury forces that are present in the pelvic floor; correct?

A. No. I want to demonstrate what happens to a pore if you applied some forces.

Q. Okay.

A. And you see the pore collapse. That is a fact.

Q. Now, when you tested the mesh like you did in Exhibit 0697, you attached one end of the mesh to one point and then pulled it in one direction; correct?

A. Yes.

Q. And if you could show that to the jury. Hold one end and pull.

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A. (Complying.)

Q. And that's how -- that's how you tested it in your study; correct?

A. Yeah. Similar to the way Ethicon did it.

MR. THOMAS: Move to strike after "yes."

BY MR. THOMAS:

Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct?

A. If you're talking of this study, yes.

Q. Now, in the body, mesh undergoes forces from multiple directions, doesn't it?

A. It depends whether it functions as a replacement of ligaments or whether it is a function as a flat area, but, of course, you always have forces from all sides wherever you are in the world. But if you are thinking of ligaments, the relevant forces are -- should be -- or should -- it should be possible to estimate them if you're thinking of uniaxial, from one direction.

Q. And when you place the mesh in the body -- spread out the net --

A. (Complying.)

Q. -- tissue goes into the pores; correct?

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A. Yes.
Q. And it's applied tension-free so that the tissue in the pores is what actually holds the mesh into place; correct?
MR. ANDERSON: Objection.
Go ahead.
THE WITNESS: Yes.
BY MR. THOMAS:
Q. And you've not done any testing of mesh with tissue in it, have you? Excuse me. Strike that.
You have not done any effective porosity testing of mesh with tissue in it, have you?
A. We didn't do -- it is impossible to do it with this machine, to have a testing of the effective porosity, a measurement of the effective porosity with tissue inside.
Q. Okay. And you know that it's possible to design a test that tests the forces on the mesh from multiple directions, don't you?
A. I know that there are experimental settings doing this, but it is a -- it is impossible to model the situation in a pelvis in -- with any of these settings completely. It's -- every time -- everything is just an arbitrary trial that you can

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try to model it, but it's not -- never perfect.
Q. But you agree it's possible to construct a test that measured forces applied in different directions of the mesh; correct?
A. You can make a setting where you apply some forces from two directions, but it never reflects a situation of a mesh that is incorporated into tissue. Never.
Q. So when --
A. There's no way.
Q. When you -- you can design a -- strike that.
When mesh is implanted in the human body, the stresses that are applied to that mesh are both lengthwise, top to bottom, diagonally; correct?
A. It depends from the location and of the function and of the size of the mesh whether the model has to include these differences or whether it's possible to just think of one direction, and all mechanical testing setups are insufficient or computer simulations until now are insufficient to model this.
Q. Well, it's true that there are a variety of forces that are applied to a mesh in placement in the pelvic floor; correct?

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A. Yes.
Q. And it's not only the one directional force that you used in your test model; correct?
A. The one direction force is the best approximation for the ligaments, for the arms.
Q. But my --
A. Not for the others. I agree. Not for the flat mesh area. Then it is not the best way.
Q. And it's possible to design a test that allows for mesh being pulled in multiple directions and also to account for weight on the top of the mesh?
A. As I said, no. Not sufficiently. You can design such a test where you put forces from various directions, but the interpretation of these results is very difficult; and overall as a setup to reflect the situation in the body, it is insufficient.
Q. As a matter of fact, the test that you did in both 2007 and 2013 is insufficient to determine the extent to which this test can be applied to the development of better meshes; correct?
A. No.
Q. Let me show you -- go back to your study, Plaintiff's 0697.

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In 2013, the last sentence of the abstract, it says, "The clinical studies have to prove whether devices with high porosity as well as high structural stability can improve the patient's outcome."
Did I read that correctly?
A. Yes.
Q. And in 2007 --
MR. THOMAS: Can I have a sticker, please.
I'm going to mark this as Klinge Trial Deposition Exhibit Number 1.
- - -
(Klinge Trial Deposition Exhibit No. 1, Article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped DX31026.1 through DX31026.8, was marked for identification.)
- - -
BY MR. THOMAS:
Q. Let me show you what I have marked as Klinge Trial Deposition Exhibit Number 1.
MR. ANDERSON: Thank you.
Q. Klinge Trial Deposition Exhibit Number 1 is the first study that you and Professor Mühl conducted back in 2007; correct?

A. Yes.
Q. And in this study, you and Professor Mühl did uniaxial testing on DynaMesh and other meshes manufactured in Europe; correct?
A. Yes.
Q. And you found in 2007 that the DynaMesh retained its effective porosity and the other meshes did not; correct?
A. No.
Q. Not true?
A. No, that's not true.
Q. Did DynaMesh retain its effective porosity?
A. Yes, but Sofradim light as well.
Q. Okay. And at the end of the study in 2007, you say that, in the abstract, "Further in vivo studies have to investigate whether the preservation of a high effective porosity under stress may help to improve biocompatibility of textile implants."
Is that correct?
A. Yes.
Q. And "in vivo studies" means studies in animals?
A. Amongst all, but more or less the most important way to learn what happens to the meshes is

the analyses of explanted materials from humans.
Q. Okay. The study says further in vivo studies. That means studies of mesh in animals; correct? Isn't that what that means?
A. I guess at that time we thought that -- this was a setting in a lab without any tissue, without any biology, and we said this testing from the lab has to be transferred to the biology, and this -- therefore, we said we need this in vivo studies, and there's no specification to animal or reduction to animals.
Q. There have been no in vivo studies to investigate whether the preservation of a high effective porosity under stress may help to improve biocompatibility of textile implants, has there?
A. Not before, because this was the presentation of this -- this conception.
Q. And in 2013 in Exhibit 0697, you repeat, the clinical studies have to prove whether devices with high porosity as well as high structural stability could improve the patient's outcome. There's still no clinical studies that prove wherefore devices with high porosity as well as high structural stability can improve the patient's outcome, are there?

A. The problem that they are not there are because the old meshes, the small pore meshes, as Prolift, they all belong to the category of these small pore thing.
Q. Okay.
A. How we don't have sufficient explants from large pore materials with a high structural stability in the moment, but we are still collecting these materials.
Q. Can you answer my question yes or no? Let me ask it again.
In 2013, Doctor, you state in this study, "Clinical studies have to prove whether devices with high porosity, as well as high structural stability, can improve the patients' outcome."
There's still no clinical studies that prove whether devices with high porosity as well as high structural stability can improve the patients' outcome; true?
A. There are no comparative clinical studies at all.
Q. Thank you.
Now, Doctor, in this study in both 2007 and in 2013, you identified 1,000 microns or 1 millimeter

as the standard of effective porosity in polypropylene; correct?
A. Yes, that is what we used.
Q. But you used 600 microns for PVDF; correct?
A. Yes.
Q. Now, it's true in the context of effective porosity, if a pore is reduced by even 10 microns, to 990 microns, it does not get counted in a porosity calculation; correct?
A. That is correct.
Q. And so it's only pores with 1,000 microns in all directions that are included in the effective porosity calculation; correct?
A. That depends on the polymer. If you have another polymer where you know that it behaves a little bit better, then it is very easy to change the machine. It is objective, reproducible, reliable. So if you, as a manufacturer, have a polymer where you know that it is -- critical diameter would be only 900 microns, yeah, then you can make these measurements with your critical diameter.
Q. Okay. And the machine --
A. Our data, we, up to now -- we just had the data of 1,000 for polypropylene and 600 for PVDF,

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but -- yeah.
Q. But you didn't -- those are the only two measurements you took, at 1,000 for polypropylene and 600 for PVDF; correct?
A. Measurements, there have been a lot, but these are the two, yeah. If you applied this measurement to this machine for polypropylene, you can put in only one range.
Q. Okay.
A. One limit.
Q. You know, other scientists disagree with your 1,000 figure for polypropylene, don't they?
A. I'm not aware of anyone who said that the pore size and the bridging does not happen, no.
Q. Okay.
A. And I don't know any measurements showing that it is different.
MR. ANDERSON: Keep this separate.
- - -
(Klinge Trial Exhibit No. 2, Article entitled "Synthetic and biodegradable prostheses in pelvic floor surgery," Bates stamped DX3036.1 through DX3036.11, was marked for identification.)
- - -

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BY MR. THOMAS:
Q. Let me show you what's been marked as Klinge Trial Exhibit Number 2. It's an article by Deprest and others.
A. Yes.
Q. Are you familiar with this article?
A. I think a long time ago I read it.
Q. And this is an article in 2005?
A. Yes.
Q. About the same time that you came out with your article about 1,000 millimeters; correct?
A. Obviously.
Q. And do you know Dr. Deprest?
A. Yes, very well.
Q. And he's writing about synthetic and biodegradable prostheses in pelvic floor surgery; correct?
A. Obviously, yeah.
Q. If you turn to page 4 of Klinge Trial Deposition Exhibit 2, there's a description of Type I meshes. Do you see that?
A. Yes.
Q. And it includes in Type I meshes, described them as totally microporous; correct?

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A. He used another classification.
Q. Okay. That's my point. He describes the synthetic implant materials for Prolene and Marlex as totally microporous; correct?
A. That is correct.
Q. And he disagrees with your classification?
A. No. No. There is no -- not any data showing that the bridging doesn't occur. There is not any data that 1 millimeter is not a critical limit. The only thing that happens is he used the classification of Amid, who was produced when we start -- before we started our joint collaboration with Ethicon, and at that time there hasn't been any large pore mesh. So Amid was not able to consider these large pore meshes in his classification. So when using this old classification, of course, you will have a mix of these terms.
Q. Okay.
A. But it doesn't -- is relevant in any way to the fact that small pores have an increased risk, makes it unsafe and are filled by scar tissue.
Q. Go to the bottom.
A. So no.
Q. I'm sorry. Go to the bottom of page 4.

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A. Yeah.
Q. And Dr. Deprest says that, "Pore sizes greater than 75 microns allow for rapid ingrowth of fibroblasts and vascular elements necessary to anchor the implant within the native tissue."
That's what he says, isn't it?
A. Yes.
Q. Okay. Is that correct?
A. The fact is --
Q. Is it correct?
MR. ANDERSON: Is what correct?
BY MR. THOMAS:
Q. Is that statement correct? Do you agree with that?
A. The statement is only correct if you assume that you need a pore size of 75 microns to allow scar to get integrated. Our point is that we want to separate the integration of fat and scar, and, therefore, you need a completely different size of the holes. If you are agreed that you want to have scar in your implant, then, of course, yeah, this is correct.
Q. So you --
A. But it's a completely mix-up of the -- and

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there is no fact to it. It is a citation of Amid's classification and nothing more.

Q. Okay. You could have changed the settings on your effective porosity testing to measure for 75 microns; correct?

A. Everyone can do it. Yeah.

Q. But you didn't do that?

A. No.

Q. Let me show you now what's been marked as -- and, by the way, he was joined in that study by eight other people on the study; correct? On the first page you can count the people who were involved in the study.

A. Yeah.

- - -

(Klinge Trial Deposition Exhibit No. 3, Article entitled "The biology behind fascial defects and the use of implants in pelvic organ prolapse repair," Bates stamped DX30360.1 through DX30360.10, was marked for identification.)

- - -

BY MR. THOMAS:

Q. Let me show you now what I have had marked as Klinge Trial Exhibit Number 3. And this is a --

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another paper a year later by Dr. Deprest; correct?

A. Yes.

Q. It's in 2006. This is a year after your paper; correct?

A. Yes.

Q. And if you'll go to page 3 of this trial Exhibit 3, once again, he cites to the Amid classification; correct? Down on the right, lower right-hand corner?

A. Yes.

Q. And you see the classification of implants where it talks about macroporous -- that's with an a -- that's greater than 75 microns. Do you see that?

A. Yeah.

Q. And it says in the lower right-hand side that, "Pore sizes greater than 75 microns allow for rapid ingrowth of fiberglass and vascular elements necessary to anchor the implant within the native tissue. Peak ingrowth is reached at pore size around 400 to 500 microns."

Did I read that correctly?

A. Yeah.

Q. You didn't --

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A. The next sentence.

Q. Yes. Larger --

A. "Larger pores limit the fibrosis process to perifilament region and the pores get filled with fat."

Q. Right. But you didn't do any testing on your effective porosity machine at 400 to 500 microns, did you?

A. We didn't make a calculation exactly with this one, no.

Q. Okay. And do you agree with Dr. Deprest that in the use of implants in pelvic organ prolapse repair that peak ingrowth is reached at pore size around 4- to 500 microns? Do you agree with that?

A. If you are -- this is while you are coming from tissue engineering, and it is not the value that helps us to define whether you have fat and scar tissue. Therefore, it is no argument against the relevance of effective porosity for the clinical outcome.

Q. Okay. But you didn't measure at 4- or 500 microns, which is the peak level identified by Dr. Deprest, did you?

A. In what -- in what sense should --

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Q. Yeah. You didn't conduct those tests on --

A. If --

Q. -- either DynaMesh or on polypropylene in the tests you did with Professor Mühl; correct?

A. If we place a mesh into this machine and defined the critical size of, let's say, 200 microns, yeah, there will never be an effective pore -- pore that will be filled by fat tissue.

Q. My --

A. We know this, yeah.

Q. My point is, Doctor, you didn't test at the areas identified by Dr. Deprest as being the peak ingrowth for tissue as cited in the exhibit I just gave you. You've not done that, have you? True?

A. But in the --

Q. Is it true?

A. We never modified this testing with these data, yes, that is true.

Q. Okay.

A. But it doesn't make any sense.

- - -

(Defendant's Exhibit No. DX30064, Article entitled "Classification of biomaterials and their related complications in abdominal wall hernia

surgery," Bates stamped DX30064.1 through DX30064.7, was marked for identification.)

BY MR. THOMAS:

Q. All right. And you know that there are some people -- let me show you what's been marked as Defendant's Exhibit 30064, and 30064 is the Amid paper from 1997. You recognize that?

MR. ANDERSON: I'm sorry, Counsel. Is this going to be a defense exhibit? Because the other ones you used a defense exhibit for Klinge. Do you want it to be a Klinge exhibit? Because you --

MR. THOMAS: I know that. And just for your benefit and my admission, I didn't realize when I marked them that they had numbers on them. All I'm trying to do is not create new numbers if I can.

MR. ANDERSON: Okay.

MR. THOMAS: And we'll change -- we'll change the numbers at a later time if I have to.

MR. ANDERSON: So that it correlates with your exhibit numbers. Okay. That's fine.

MR. THOMAS: I'm just trying to identify them

as best I can.

MR. ANDERSON: Yeah.

BY MR. THOMAS:

Q. Now, Doctor, I've shown you Defendant's Exhibit 30064, and this is the Amid paper that we have been talking about, isn't it?

A. Yes.

Q. And this is what has been known as the Amid classifications since 1997; correct?

A. Yes.

Q. And you know that there's some people that still follow the Amid classification; correct?

A. I personally will follow it when -- when looking at the risk for infection and material infection, I -- it's still proper to follow this classification. If you want to separate the bridging fibrosis, the scarring of the pores, it is not appropriate.

Q. But that's you. You know that there are some scientists who still follow the Amid class at this indication?

A. Depends on the purpose why.

Q. Okay. Thank you.

A. What do you want to have with the -- yeah.

Q. It's fair to understand, Doctor, that the two studies that you did with Professor Mühl that we've had marked one as Plaintiff's 0697 and the other as Klinge Trial Exhibit Number 1, are not, standing alone, able to replicate what happens in the human body; correct?

A. They are able to replicate some aspects.

Q. Okay. But the whole point of these studies is to give people a starting point so that you can use this information to develop a better model to understand what happens in the human body; correct?

A. It helps to predict the risk for rigid fibrosis without any forces and what happens to your textile, to your device when you applied some forces. Therefore, it gives a measure so that you can optimize the design of the meshes, yeah.

Q. Uniaxial forces only; correct?

A. Uniaxial forces, yeah. And you can modify the forces. You can modify the diameter depending on the polymer you are using. So a very standardized technique, open for everyone.

Q. And so when you go back to Plaintiff's 0697 and you go to page 5 --

MR. ANDERSON: Hold on. Let's get 06 --

that's not it.

MR. THOMAS: It's the 2013 study.

MR. ANDERSON: Yeah. But I moved stuff. Here.

THE WITNESS: Five.

BY MR. THOMAS:

Q. Are you there? The porosity of the Gynemesh PS and the Gynemesh -- and the DynaMesh, I'm sorry, are measured, on the very top of that article. Do you see that?

A. Where are you?

Q. Is that textile porosity where it says porosity at percentage?

A. I guess it's the textile porosity.

Q. Okay. Do you know what it is?

A. The textile porosity is the area that is not covered by the ligaments.

Q. Okay.

A. So maybe this is the easiest definition of this one.

Q. Do you know under Gynemesh where it's 62.9, do you know what that represents?

A. Where you are?

Q. Under porosity at the top in the figure, in

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Figure 3 on the far left. Doctor -- Doctor, if you look at page 5 --
A. Yeah.
Q. -- of Exhibit 0697, I'm looking at Gynemesh PS with no force, zero newtons per centimeter, under arm 1, and there's a figure 62.9.
A. Yeah.
Q. What does that mean?
A. That means when you made an image, that 67 -- 62.9 percent of this area is not covered by filaments.
Q. Okay. And that's arm 1; correct?
A. That's arm 1.
Q. And then arm 3 is 60.1; correct?
A. Yeah.
Q. And if you compare that with DynaMesh arm 1, that is equal to or greater than the value for DynaMesh; correct?
A. Yes.
Q. Okay. Now, you agree that biocompatibility of long-term implantable devices can be defined as the ability of the device to perform its intended function with the desired degree of incorporation in the host without eliciting any undesirable, local or

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systematic effects in the host?
A. Yes.
Q. And you know of no studies -- strike that.
You agree that Prolene Soft Mesh has a better biocompatibility than the Prolene mesh used in hernia repair?
A. It depends on the specific design and -- of the different -- it depends from the location and --
Q. Do you have an opinion --
A. -- to place it.
Q. Do you have an opinion about whether Prolene Soft Mesh has a better biocompatibility than Prolene?
A. I cannot answer it. I have an opinion, but it cannot be answered just by yes or no.
Q. Okay.
MR. ANDERSON: I have the same objection. Outside the scope of direct.
BY MR. THOMAS:
Q. And you know of no studies in a randomized controlled trial which compare the biocompatibility of Prolene Soft Mesh with another mesh; correct?
A. There is no way to make a clinical trial where this question with sufficient statistical power.

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Q. Okay.
A. There's no way.
Q. So the answer is there are no studies?
A. There are no studies proving the safety or the superiority of any of these devices.
Q. Now, Doctor, when we talked about in vivo studies, we're talking about studies conducted in animals; correct?
A. It's one part, yeah.
Q. And you used rats in studies to help determine types of inflammatory reactions which occur with implanted meshes, haven't you?
A. In this collaboration that we started together with Ethicon, we used rats, rabbits and other animals. So depending on the specific question, we need different models.
Q. And the reason why you did that was so that you could place mesh in animals and study the tissue response to that mesh; correct?
A. Yes.
Q. And you also used rats in studies to determine the extent to which mesh integrates into the tissues of the rat?
A. As I told you, we use rats, rabbits, but we

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confirmed all these results by looking at the human explants.
Q. And the reason why you wanted to -- strike that.
You used rats in studies to determine the extent to which the mesh implanted into the rat integrates into the tissues; correct?
A. I didn't get the entire question.
Q. Let me ask it again.
In your experience, you use rats in studies to determine the extent to which the mesh implanted in the rats integrates into the tissues of the rats; correct?
A. Yes.
Q. Okay. And you know that Ethicon has conducted tissue reaction and tissue integration studies where Ethicon implanted mesh in animals, don't you?
A. Yes, I know.
Q. And you have reviewed some of those studies; correct?
A. Yes.

(Klinge Trial Exhibit No. 4, Ethicon Final

Report, PSE Accession No. 00-0035, An Exploratory 91-day Tissue Reaction Study of Polypropylene-based Surgical Mesh in Rates (PSE ACC. NO. 00-0035), was marked for identification.)

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BY MR. THOMAS:

Q. I'm going to show you what I have marked as Klinge Trial Exhibit Number 4.

Dr. Klinge, Klinge Trial Exhibit Number 4 is a document titled -- document dated July 11, 2001. It's a final report, and it's titled, "An Exploratory 91-Day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats."

You've seen that before, haven't you?

A. I think I saw it, yeah.

Q. And you reviewed that in connection with your work in this litigation, didn't you?

A. Yes.

Q. And you did not see this study before this litigation; correct?

A. That is correct.

Q. And Ethicon conducted this study in the period 2000 to 2001; correct?

A. It should be correct.

Q. And let's go to page 2 of 27 of this study.

A. Two of 27.

Q. See under "Summary"? Right there under "Summary."

The first line, "A subcutaneous implantation study was conducted to assess the tissue reaction profile and qualitative integration of several different constructions of polypropylene surgical meshes."

Tell the jury what a subcutaneous implantation study is.

A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath -- underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able, then, after some time that you can explant the material and look to the tissue reaction to this.

Q. Okay. And you can look to both the tissue reaction, which is the -- how the body reacts to the mesh; correct?

A. Yes.

Q. And the qualitative integration of the mesh. That means the extent to which the tissue integrates

into the mesh; correct?

A. You have to define it very carefully what -- what type of tissue, what are -- which cells you are looking at, what happens in the pores, which is your area of interest. So research is not so simple just to say we are making it and looking to this, no.

Q. Okay.

A. It is --

Q. You understood that this study placed mesh under the skin of rats --

A. Yeah.

Q. -- in order to look at the tissue reaction to that mesh as well as to analyze the extent to which the tissue integrated into the mesh. You understand that was a goal of this study?

A. Yeah. We did it several time ourselves but --

Q. Same type --

A. -- we know the limitations of this very, very well.

Q. I understand. But you've done this same type of study yourself with different animals and different meshes?

A. And for some other purposes with this

specific hypothesis, yeah.

Q. Okay. And if you turn the page, please, it talks about materials. Do you see that?

A. There we are.

Q. We're on page 3 of 27 --

A. Yeah.

Q. -- of Klinge Trial Exhibit Number 4.

A. Uh-huh. Bard, Surgipro, Prolene and Prolene Soft, Vypro.

Q. And there are listed there seven different meshes that are tested; correct?

A. Yes.

Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon?

A. No, no, no.

Q. Excuse me. Bard mesh is not made by Ethicon; correct?

A. That is correct.

Q. Thank you.

And that's what you referred to as a small pore heavyweight mesh; correct?

A. Yes.

Q. Surgipro mesh, likewise, is a mesh

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manufactured by a competitor; correct?
A. Yes.
Q. Now, Prolene mesh is a -- is the hernia mesh used by Ethicon that has a pore size smaller than the Prolift mesh; correct?
A. How -- what is your definition of the pore size and how it is measured? What is the pore size of the Prolift mesh? So it is insufficient. We know it meanwhile to give just one figure.
Q. Without tension it is clear that the pore size of the Prolene mesh used in hernia repair is smaller than the --
A. The area of affected pores maybe.
Q. Let me ask the question again, and let me finish it before you give an answer.
A. Sorry.
Q. Doctor, it's true that the area of the pore for the Prolene mesh used in hernia repair is smaller than the pore size without tension of the pore size of the Prolene polypropylene mesh used in Prolift?
MR. ANDERSON: Objection.
THE WITNESS: Again, it would be necessary to make a testing of the effective porosity for the Prolene mesh. I didn't do it, so I know -- I

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don't know it.
BY MR. THOMAS:
Q. I'm not talking about effective porosity. I'm not -- I'm talking about porosity at rest without tension.
A. The textile porosity --
Q. Yes.
A. -- you mean.
Q. Well, if you want to call it textile porosity, that's fine.
A. But this is essential, because we are sticking to the effective porosity. We wanted to know what happens to the tissue. The textile porosity is not relevant, so --
Q. Okay. To you.
A. There are no figures about this.
Q. Okay. The company used, in its study, Prolene mesh, which is the same mesh used in hernia repair. You agree with that?
A. There has been a Prolene mesh used in hernia repair, though there are some modifications. It is not clear which modification exactly was used here, but, yeah.
Q. Okay. And the company also tested Prolene

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Soft Mesh; correct?
A. Yes.
Q. And the company tested Vypro mesh. You see that?
A. Yes.
Q. And it tested three different kinds of Vypro mesh. Do you see that?
A. Yes.
Q. And Vypro mesh is the mesh that you helped Ethicon develop; correct?
A. Yes.
Q. And Vypro mesh is the mesh that you characterize as being lightweight large pore; correct?
A. Yes.
Q. And the company in Klinge Trial Exhibit Number 4 compared the tissue reaction and tissue integration of all seven of these meshes; correct?
A. Yeah.
Q. And they implanted these meshes in rats for 7 days, 28 days, 63 days, and 91 days; correct?
A. Yeah, that is correct.
Q. And after each of these time frames, some of the rats were killed, sacrificed, and then the mesh

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removed so it could be analyzed; correct?
A. Yeah.
Q. And when you removed the mesh from the animal to be analyzed, how do you prepare samples? What's the proper way to prepare samples?
A. Usually the tissue sample is fixed in formaldehyde, and then later on it is -- it is put into a paraffin so that you can make some sections of it, and then later on it's stained.
Q. And so the formaldehyde is added to the samples upon withdrawal not only as a preservative but to fix the tissue in place; correct?
A. To stop the degradation of the tissues. If you don't use formaldehyde and you're storing some tissue at home, you will see a catastrophe. It will be destroyed within some few days.
Q. And after the mesh is then cut into slides from the paraffin, a study pathologist looked at these slides; correct?
A. Someone is looking sometime, yeah.
Q. Well, you know that a pathologist in this case looked at the slides. Do you know that?
A. In this case, yeah. But it's not necessary that it has to be a pathologist.

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Q. But a pathologist is what? What's a person -- what's a pathologist do?
A. A pathologist is someone who has the training to investigate tissues that are extracted by some surgical means or from some tissues, and there he was trained to identify the changes in these tissues.
Q. Now, you didn't work at the institute of pathology at your hospital, did you?
A. No.
Q. And you don't -- you didn't do a residence in pathology, did you?
A. No.
Q. And you had no fellowship in pathology, did you?
A. No.
Q. As a matter of fact, you're not permitted to sign pathology reports at your hospital; correct?
A. That is correct.
Q. Now --
A. But in research, the examination never is done by the pathologist but by the researcher themselves.
MR. THOMAS: Object. Move to strike everything after "that's correct."

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BY MR. THOMAS:
Q. Let's go to page 2. And page 2, the third line down under "Summary," the summary finds, "The inflammatory reaction among the different constructions was relatively similar, ranging from minimal to mild in intensity and, thus, were all considered to be biocompatible."
Did I read that correctly?
A. Yes.
Q. If you go to page 9, first line of the second paragraph on page 9, page 9 of 27 up at the top. "Study found that all of the meshes had sufficient porosity to allow for integration with surrounding connective tissue."
Did I read that correctly?
A. Yes.
Q. And, Doctor, when people conduct studies, they make these slides that you referred to with the tissue samples; correct? So that they can be looked at under a microscope, that's what you do; correct?
A. Again?
Q. When studies, like Klinge Trial Exhibit Number 4, conducted the tissue that's removed from the slices, the paraffin, it's made into slides to put under a microscope; correct?
A. Yeah.
Q. And it's the microscopic observation by the person looking at it that causes him to reach the conclusions that they express in the report; correct?
A. No, not always. You have to look to the microscopical appearance of the explants as well. So the microscopical mainly is an explanation of what happens, but for the patient it's more important what happens clinically.
Q. You've never looked at the slides that this study generated in Klinge Trial Exhibit Number 4, have you?
A. I never got the slides from this study from study from Barbolt. I've seen it.
Q. And you know they're still available, don't you?
A. What?
Q. You know they're still available, don't you?
A. They are still available?
Q. Yes. You haven't looked at it?
A. I didn't get it, yes.
THE WITNESS: Is it possible to get?
BY MR. THOMAS:

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Q. Let's go to Plaintiff's Exhibit 271. That's your 2005 paper.
MR. ANDERSON: That's not it.
BY MR. THOMAS:
Q. And this is a paper that you prepared with Dr. Klosterhalfen and Dr. Junge?
A. That is correct.
Q. And would you call this a review article?
A. Yes.
Q. And you're kind of reviewing the state of medicine and science on the concept of lightweight and large pore mesh for hernia repair in this paper; correct?
A. Please can you repeat the question, the details?
MR. THOMAS: Can you read that back, please.
THE COURT REPORTER: "And you're kind of reviewing the state of medicine and science on the concept of lightweight and large pore mesh for hernia repair in this paper; correct?"
THE WITNESS: And "you're kind"?
MR. THOMAS: I'm sorry.
THE WITNESS: I don't understand the first words.

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MR. THOMAS: That's my fault. I apologize.
BY MR. THOMAS:
Q. The purpose of this article, Plaintiff's 2071, is to review the state of science and medicine on the mesh concept known as lightweight and large porous for hernia repair?
A. Yes, that is --
Q. Thank you.
A. -- true.
Q. And in here you talk not only about old meshes but also new meshes; correct?
A. The new generation mesh, yeah.
Q. And in the abstract, which is on the first page of 2071, you state that: "All experimental evidence and first clinical data indicate the superiority of the lightweight large porous mesh concept with regard to a reduced number of long-term complications and particularly increased comfort and quality of life after hernia repair."
Correct?
A. That is correct.
Q. And what you're referring to there are your initial results; correct?
A. What is your definition of "initial"?

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Q. Well, there's certainly --
A. It is what we know to this time point.
Q. There are no long-term studies available to determine the extent to which lightweight large pore mesh behaves better than small pore heavyweight mesh, as you've described them in this study, at the time that you published this study?
A. At this time, no, not to my knowledge.
Q. Okay. Let's go to page 112, please.
I don't think that's the right page, Doctor. 112.
MR. ANDERSON: 112?
MR. THOMAS: Under --
MR. ANDERSON: You're reading off of your exhibit number, but you said go to Plaintiff's Exhibit, so ours doesn't have your -- do you have your trial exhibit number?
MR. THOMAS: I'm looking at this number right here, 112. Is that different than yours?
MR. ANDERSON: Yeah. Maybe yours is different. Let's see. Did you -- did you give me your exhibit?
MR. THOMAS: You already -- it's already in the record, so I didn't.

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MR. ANDERSON: Yeah. But your version is different from this version because you've got yours stamped at the bottom.
THE WITNESS: Do you have the pages?
MR. ANDERSON: And we don't have the stamped.
THE WITNESS: We don't have the same pages.
MR. THOMAS: I'll do it from your document. Let me see if I can find the page. I wonder why it's different.
BY MR. THOMAS:
Q. Let's go to page 10 of Exhibit 0271, please.
Do you have page 10?
A. Yes.
Q. On page 10 you and your coauthors begin talking about the new generation of lightweight large porous meshes, Vypro and Vypro II; correct?
A. Yes.
Q. And is the purpose of this discussion to talk about the promise of Vypro and Vypro II in hernia repair; correct?
A. The purpose of what?
Q. The promise.
A. Promise?
Q. The future potential benefits of Vypro -- let

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me ask the question again.
On page 10 of Exhibit 0271, there is a paragraph titled "The New Generation: Lightweight Large Porous Meshes." Correct?
A. Yes.
Q. And in that paragraph, series of paragraphs, you discuss Vypro and Vypro II?
A. Yes.
Q. And those -- Vypro I is the mesh that you helped develop with Ethicon for hernia repair; correct?
A. Yes.
Q. And Vypro II was a subsequent development of Vypro again in hernia repair; correct?
A. Yes.
Q. And the bottom of that paragraph or that section says that, "First clinical trials confirm the expected superiority of the lightweight large porous mesh concept concerning quality of life after hernia repairs."
What does "quality of life after hernia repair" mean?
A. It depends from the -- from the trial that you are doing. Quality of life -- to measure quality

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of life, there are different tools depending on the investigator. It can be looking to foreign body sensation. It can be looking to pain. It can be looking to serious complications. So a lot of these things. And there are some attempts to quantify them. There are some questionnaires, as SF-36, which gives a lot of data. So you try to quantify quality of life to know what happens to the patient.

Q. Okay. And is the quality of life an appropriate end point for a study to determine whether a mesh implanted in the body is functioning appropriately?

A. It's usually a secondary end point. It's --

Q. Secondary to recurrence?

A. Yes.

Q. Okay.

A. Usually.

Q. All right. But it's an important end point to understand how a patient's quality of life has been affected by the hernia repair; correct?

A. It's one way to measure this.

Q. And at this time there are no long-term studies on Vypro and Vypro II to determine the quality of life for these patients after hernia

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repair; true?

A. So far I remember the long term is there one, two years maybe. I don't know exactly the Brinkman study when it came up, when it was published there. It was about three years, so it depends from what you are thinking of long term.

Q. And under polypropylene, next paragraph down, you say, "Most manufacturers have added to their range of polypropylene heavyweight mesh small porous mesh modifications, lightweight large porous adaptation."

Correct? Did I read that correctly?

A. Yeah. Yes.

Q. And if you go to the last sentence in that section it says, "However, clinical trials have yet to confirm the promising preclinical results."

Now, what does that mean?

A. That means that at that time we hoped that it is possible to make the clinical trial and to demonstrate that one material is superior to another just by operating 150 patients in this direction or -- and 150 patients with another mesh, and we did some prospective clinical trials with Ethicon together to get this information; but we learned that

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it is not possible at all to do this confirmation at clinical studies.

Q. At the time that you published Exhibit 2075, there were no clinical trials available to confirm the promising preclinical results of the lightweight large porous polypropylene mesh that most manufacturers have added; correct?

A. So it is correct --

Q. Thank you.

A. -- in regard to comparing studies.

Q. Okay.

A. It is not correct in regards to the analysis of explants.

MR. THOMAS: All right. Move to strike everything after "it's correct."

BY MR. THOMAS:

Q. You also discuss on page 11 of Exhibit 0271 Ultrapro; correct?

A. Yes.

Q. And Ultrapro is the mesh that you understand to be the predominant mesh used in hernia repair in Germany; is that correct?

A. So far I know, yes.

Q. And at the end of your discussion of

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Ultrapro, you say, "Overall the Monocryl polypropylene composite Ultrapro is currently the member of the lightweight large porous mesh family with the lowest foreign body reaction and optimized handling. The first clinical studies produced encouraging results to move forward with this mesh concept."

Correct?

A. Yes.

Q. And I believe you've already told me that you do not think that Ultrapro -- strike that.

Ultrapro is the same mesh as Prolift+M; correct?

A. Prolift+M used the Ultrapro.

Q. Okay. And you do not believe that Ultrapro, known as Prolift+M, is appropriate for use in the pelvic floor; correct?

A. This work is focused on the tension-free situation in the abdominal wall without applying any forces to it. At that time we didn't think that someone is using this mesh for a situation where you applied some forces; and, therefore, Ultrapro is still the mesh I think with the largest pores and, therefore, with a pretty nice tissue integration if

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applied without any force and tension and if it's laying flat.
Q. Is it your opinion that Ultrapro should not be used for abdominal hernia repair?
A. For abdominal hernia repair there is, of course, an indication to use it.
Q. Okay. And so is it your opinion that Ultrapro is appropriate for abdominal hernia repair, but the same mesh in Ultrapro, which is in Prolift+M, is not appropriate in the pelvic floor?
A. It doesn't matter in what tissue you are using it. It is -- you should use it in a tension-free way so that it's laying as an area, as a flat mesh there. If you apply some tension -- and we made ourselves experiments using the Ultrapro close to the diaphragma where we applied some tension to it and got disappointing results with the Ultrapro. So it depends on the specific indication function of these devices.
Q. And surgical technique?
A. If you are free -- if you are free, of course, with the surgical technique you can do every complication that is imaginable, but there are some procedures that need some forces, and in these cases

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this mesh is not a good alternative. It's not a safe alternative.
Q. And when you speak about "this mesh," you're talking about Ultrapro?
A. Ultrapro.
Q. Okay.
A. Yeah, you talk.
Q. Is there any mesh that you've identified that's appropriate for use in the pelvic floor for the repair of pelvic organ prolapse?
A. I cannot give a general statement to this. I know that there are textile constructions and design for meshes that are more resistant to the collapse, but it depends on the indication of the specific situation. There is never one device for all diseases in the pelvic floor. No, it's not done. It has to be very carefully designed for the specific purpose.
Q. And you've not designed a specific mesh for the treatment of pelvic organ prolapse; true?
A. No. I'm only asked sometimes whether this fits our -- whether the device of the FEG, where I am a consultant, fits to these principles of less material, large pores and stability of the structure.

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Q. You answered my question no, so I need to answer it again -- ask it again.
It's true that you have never designed a mesh for the treatment of pelvic organ prolapse; true?
A. I was involved in the design process in regards to the question whether the textile design fulfills these requirements, but, of course, I'm not entirely manufacturing or designing meshes for the pelvic floor.
Q. And can you identify for me any mesh available in the United States today that is -- where the benefits outweigh the risk for the treatment of pelvic organ prolapse?
A. You cannot answer this question because it's a general statement. It doesn't make any sense.
Q. Okay. Since the work that you've done -- strike that.
Since your 2005 article that you've just described, there have been long-term studies comparing lightweight large pore mesh against small pore heavyweight mesh, haven't there?
A. There has been published several studies, yeah.

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(Klinge Trial Deposition Exhibit No. 5, Article entitled "Long-term outcome and quality of life after open incisional hernia repair - light versus heavyweight meshes", was marked for identification.)

BY MR. THOMAS:
Q. Let me show you what's been marked as Klinge Trial Exhibit Number 5. It's a research article titled "Long-Term Outcome and Quality of Life After Open Incisional Hernia Repair, Light Versus Heavyweight Meshes." First author is Ladurner. Have you seen this study?
A. I guess I have seen it, yeah.
Q. And this is a long-term study of up to 72 months after incisional hernia repair with lightweight meshes compared to heavyweight meshes; correct?
A. Yeah.
Q. And the heavyweight mesh is a Prolene mesh. The lightweight mesh is your Vypro mesh; correct?
A. Yes.
Q. And the two groups were equal in body mass index, age, gender and hernia size; correct?

Is that correct?
A. Age and gender you said?
Q. If you look in the abstract, see in the abstract?
A. Yeah.
Q. It says right in the middle under "Methods," "The two groups were equal in BMI," which is body mass index, "age, gender and hernia size." Correct?
A. Yeah. I'm looking to the data there, so hernia size almost -- it's -- yeah.
Q. Okay. And it finds in the conclusions, "In this study the health-related quality of life based upon FS36 survey after open incisional hernia repair with light or heavyweight meshes is not related to the mesh type in the long-term follow-up."
Did I read that correctly?
A. You read this correctly.
Q. And what that means is that the kind of mesh that was used in the hernia repair did not affect the long-term quality of life in the patients in this study; true?
A. No. Because it is ridiculous to take this study with 12 patients in one group and 12 patients in the other and to make a read out with the FS36.

It is so tremendously underpowered that this statement, of course, is not confirmed by these data. It's ridiculous to discuss this.
Q. Well, it's certainly what this study reports; correct?
A. You read it correctly.
Q. Okay. And it's published in the peer-reviewed literature?
A. Yes. Maybe -- yeah. BMC should be peer reviewed, yes.
Q. Okay. But you disagree with the findings in Exhibit Number 5; correct?
A. No. The findings they describe, but the conclusion, it is underpowered. You cannot state this. So the findings, when they measured it, yeah, it can be correct. But to take 12 patients in one group and 12 in the other and come up with this conclusion, it is dangerous to do so.
Q. And the reason why is because you want to have more subjects in the study or perhaps even a registry to allow you to have more data upon which to make certain findings; correct?
A. The reason is coming from the statistics, that you need a certain amount of data to come with

this conclusion; and it is not justified. And the statistical power is just one measure. Yeah, you have to consider this. It's not because I want to have it.
Q. Let's --
A. And, therefore, it is so difficult to make a clinical trial comparing two different devices in similar patients.
Q. Let's --
A. And, therefore, we need as an alternative registry. Yes, I'm sure.
Q. Registries is the better way to go?
A. It offers the option to accumulate data from a long -- of very many patients over a long period, and, of course, the data of the registries over the time will help us to understand it.
MR. THOMAS: Let's take a break and change the tape.
THE VIDEOGRAPHER: We are off the record. The time is 12:21 p.m.
(A recess was taken from 12:21 p.m. until 12:33 p.m.)
THE VIDEOGRAPHER: This marks beginning of Video Number 3. We are back on the record. The time is 12:33 p.m.

BY MR. THOMAS:
Q. Doctor, before we were -- broke, we were talking about the limitations in randomized controlled trials, about them not being sufficiently powered; correct?
A. Yes.

(Klinge Trial Exhibit No. 6, Article entitled "Bias-Variation Dilemma Challenges Clinical Trials: Inherent Limitations of Randomized Controlled Trials and Meta-Analyses Comparing Hernia Therapies", was marked for identification.)

BY MR. THOMAS:
Q. Let me hand you what I have marked as Klinge Trial Exhibit Number 6. Klinge Trial Exhibit Number 6 is a paper you have just published on this topic, isn't it?
A. Yes.
Q. And on the first page, I guess it's a 2014 paper, titled "Bias-Variation Dilemma Challenges Clinical Trials: Inherent Limitations of Randomized Controlled Trials and Meta-Analyses Comparing Hernia Therapies." And in this paper you criticize

randomized controlled trials and meta-analyses; correct?
A. I showed the limitation of these --
Q. Yes.
A. -- or some questions.
Q. And the ultimate conclusion of this paper, Klinge Trial Exhibit Number 6, is that registries provide better information than do randomized controlled trials or meta-analyses; correct?
A. Not correct. If you believe that better is sufficient than -- that is not the purpose to have better data, but we need other data, and registries are able to provide additional data that will help us to define what is the outcome of the patients, yes, additionally.
Q. Go to page 787 of Trial Exhibit Number 6.
You see that? You see in the middle of the second paragraph it begins, "Observational studies nowadays can best be done with the help of registries, would provide a structure and a set of variables that are known to reflect all major influences on the patients' outcome. In this regard, it uses the same variables as the RSCT but did not restrict its data acquisition to a small group of

study patients."
Did I read that correctly?
A. Yes.
Q. And the purpose of that is to talk about more robust data set from a greater number of people?
MR. ANDERSON: Objection. RSCTs are outside the scope of direct.
But go ahead, Dr. Klinge.
THE WITNESS: So I'm not sure whether it's possible to reduce robust database, whether this covers all the questions that we address in this article.
BY MR. THOMAS:
Q. Do you conclude from this article that using data from a long-term registry with a large number of patients with more data is better than doing the randomized controlled trials that have been used in the past?
A. I would never say that it is better in a general term. It will help us to define the outcome of the patients, better than in -- with all the limitations of randomized controlled trials, and this is expressed on several pages there.
Q. Okay.

A. So registries should be done additionally to randomized controlled trials depending on the question, depending on the setting.
Q. And registries, just for the benefit of the jury, are sets of data that are accumulated as people go through hernia surgeries, and data is completed at the time of the surgery; correct?
A. The data are not complete yet. Registries have the advantage that you can include various kinds of patients, not only restricted to some standard patients, and you can include a follow-up of various times, very long period. There is -- in clinical studies, you usually finish after one day or one year or two years. So the registry offers a lot of more options to made a post-market surveillance quality control of devices; and, therefore, I think it is very interesting from manufacturer if they are interested in making their follow-up of their patients.
Q. Okay. Let me show you what's been marked as Klinge Trial Exhibit Number 6.
THE COURT REPORTER: It should be 7.
MR. THOMAS: Seven. I'm sorry. Let me mark on it 7. Let me have that back, Doctor, please.

(Klinge Trial Exhibit No. 7, Article entitled "Prospective, Long-Term Comparison of Quality of Life in Laparoscopic Versus Open Ventral Hernia Repair", was marked for identification.)

BY MR. THOMAS:
Q. Doctor, let me show you what I have marked now as Klinge Trial Exhibit Number 7.
Klinge Trial Exhibit Number 7 is a 2012 study, first author Colavita, titled "Prospective, Long-Term Comparison of Quality of Life in Laparoscopic Versus Open Ventral Hernia Repair."
Have you seen this before?
A. I have seen it, but it's some time ago.
Q. Okay. And if you look down at the methods, patients in this study were drawn from the international hernia registry; correct?
A. Yes.
Q. And it's 30 centers in the United States, Canada and Europe and Australia; correct?
A. Yes.
Q. And in this study the authors looked at a total of 710 hernia repairs; correct?

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A. Yes.
Q. And looked at the long-term comparison of quality of life for these 710 hernia repairs; correct?
A. Yes.
Q. And they used what's known as the Carolinas Comfort Scale. Are you familiar with that?
A. Yes, I know it.
Q. And that's -- is that similar to the SF-36 questionnaire that we talked about in the previous study?
A. It is another tool.
Q. Okay. Do you recognize the Carolinas Comfort Scale as a way to determine the quality of life in a population of patients?
A. It is a way to measure it, yeah.
Q. Okay. At the time this study was published in 2012, if you look at the first page under the abstract and conclusion, to your knowledge was this the largest prospective quality of life study comparing laparoscopic ventral hernia repair with open ventral hernia repair, or do you know?
A. I think that's -- that is true.
Q. Okay. And so what these authors did was go

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to the registry and get the data that you have just described in your previous answers in order to make their analysis of a bigger population with more data for their findings; true?
A. They are going to a registry, but the registry is not only registry because it has name. You have to go into the details, look at what variables are recorded. That was outlined in the previous paper for me.
Q. If you go to page 719 of Klinge Trial Exhibit Number 7, first paragraph on the left, midway down, the authors conclude from this study, "There was no difference in mesh sensation symptoms between heavyweight or lightweight polypropylene mesh. As mentioned earlier, both were used with similar frequency and laparoscopic and open repairs."
Did I read that correctly?
A. Yes.
Q. So across this population of 710 hernia repairs, comparing lightweight mesh as opposed to heavyweight mesh, they found no difference as to mesh sensation; correct? Is that correct?
A. They described that they found -- yeah.
Q. Okay. And if you go to page 721 of the same

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study, first full paragraph on the left, it says, "In multivariant analysis, mesh weight had no effect on pain, activity limitation, mesh sensation, or overall symptoms in the present study."
Did I read that correctly?
A. You read this correctly.
Q. And it follows down to the end of that paragraph and it says, "In a recent small comparative study of open ventral hernia repair with light and heavyweight mesh, no difference was seen in quality of life using SF-36 with long-term follow-up."
And that's the study that we looked at a minute ago, the Ladurner study; correct?
A. Twenty-seven, if this is here, the reference, 27? Yeah, you're right.
Q. The results of this study, Klinge Exhibit 7, confirms these findings -- this long-term study from the registry, Klinge Exhibit Number 7, confirms the randomized controlled trials, the Ladurner study, that we talked about before. That's what this study finds; correct?
A. It confirms that the insufficiency of this study to detect any differences. It is not possible to prove something by doing these studies, and,

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therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to say that this study proves that result is similar. It is -- it is not justified to do so.
Q. Okay. Let's --
A. Even if it's done and even if it's published, no.
Q. So you disagree with the findings in Klinge Exhibit Number -- Trial Exhibit Number 7?
A. The interpretation, yeah. It's completely not justified.
Q. Now, Dr. Klinge, you have contended for years that traditional use of hernia repair are overengineered -- excuse me. Start over again. Strike that.
Doctor, you have contended for years that traditional meshes used for hernia repair are overengineered and is stronger than is necessary for the treatment of hernia repair; correct?
A. We found this, yeah.
Q. And you have argued that a lighter weight larger pore mesh is better to accomplish the same treatment of hernia repair; correct?
A. Is better to?

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Q. Yes.
A. I didn't get every word of your question.
Q. Let me ask it again.
A. Yes.
Q. You have contended that a manufacturer can design a lighter weight larger pore mesh to accomplish the same repair of a hernia as you can with a traditional heavyweight mesh; correct?
A. No.
Q. What did I miss? You can't get the same repair with a lighter weight larger pore mesh?
A. If you're believing that you can exactly the same type of repairs with a heavyweight mesh and a large pore lightweight meshes, no, that's not true. There are indications for the different meshes.
Q. Still appropriate --
A. What we said is that you can improve the tissue integration by reduction of the material, making the pores larger, and that -- therefore, we developed together with Ethicon these large pore meshes, and this was confirmed in many animal trials, human explants.
Q. Let's go back to P1087, please.
MR. ANDERSON: Did you say 1087?

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MR. THOMAS: Yes. It's the PowerPoint.
MR. ANDERSON: I know. We just have a stack of documents, so I have to find it.
MR. THOMAS: Strike that. I'm not going to do that one anyway.
MR. ANDERSON: Okay.
MR. THOMAS: Let's go to P0260, which is a 2002 study with Dr. Klinge and Dr. Klosterhalfen.
MR. ANDERSON: Okay.
BY MR. THOMAS:
Q. Doctor, on direct examination you discussed Plaintiff's Exhibit 0260 in connection with your earlier work on talking about the impact of polymer pore size on the interface scar formation in a rat model; correct?
A. That is correct.
Q. And you used this article to talk about your findings about what happens with the smaller pore heavyweight mesh, correct, as compared to the heavyweight large pore mesh?
A. Yes.
Q. And in this study, the lightweight large pore mesh that you use as a comparator is your Vypro mesh?
A. Yes.

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Q. And that's the mesh that you helped develop with Ethicon?
A. Yes, with a pore size of 3 to 5 millimeter.
Q. And you compared Vypro against the heavyweight monofilament Marlex; correct?
A. In this article we took Marlex --
Q. Correct.
A. -- as an example of a small pore mesh.
Q. And the Marlex pore size is not the same as the Prolene Soft pore size, is it?
A. There are differences.
Q. Yes. The Marlex mesh is typically reported as a 0.6 millimeter mesh, isn't it?
A. Roughly it is assumed that it has smaller pores.
Q. And the Prolene Soft Mesh is typically described as a mesh with about 2.5 millimeters; correct?
A. I don't want to say that it is possible to reflect the pore size just by one figure. You know all the limitations of all these techniques, yeah.
Q. They are certainly different, aren't they? The Marlex and the Prolene Soft Mesh are very different in their characteristics?

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A. Yes. The soft Prolene mesh is more open than the Marlex.
Q. Okay. Doctor, you cannot point to a mesh today for use in the pelvic floor that has no risks of infection, can you?
A. There is no study -- if you -- no risks means no complication at all? No, there is no way.
MR. ANDERSON: I'll just say objection; outside the scope of direct.
BY MR. THOMAS:
Q. And, Doctor, you do not know of any mesh construction that leads to a lower -- strike that.
Doctor, you do not know of any mesh construction for use in the pelvic floor that leads to a lower erosion rate than Prolift; correct?
A. I know that there are -- that there are ways to reduce the risk. There are no clinical comparative studies, to my knowledge.
Q. Doctor, you know of -- you do not know of any mesh construction today for use in the pelvic floor that leads to a lower erosion rate than Prolift; correct?
MR. ANDERSON: Objection; asked and answered.
THE WITNESS: A mesh construction which

follows our criteria reducing the material, making it larger, it will reduce the erosion rate, but there is no comparative study available.

BY MR. THOMAS:

Q. Let me ask the question again, Doctor.

Are you aware of any mesh construction for use in the pelvic floor that leads -- strike that.

Are you aware of any mesh constructions available for use today in the pelvic floor that leads to lower erosion rates than Prolift?

MR. ANDERSON: Objection; asked and answered for the third time.

THE WITNESS: As I don't know any comparative study directly comparing different mesh structures, I only can say that there are mesh structures with lower risk than the Prolift.

BY MR. THOMAS:

Q. But you are --

A. For erosion.

Q. But you are aware of no studies that prove that point; correct?

A. No clinical studies proving this.

Q. Is that true?

A. That is true.

Q. Okay. And you are aware of no mesh construction that causes less chronic pain in the pelvic floor than Prolift; true?

A. No clinical study comparing different mesh materials and showing differences are available up to now.

Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true?

A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse. This will make a safer mesh design.

Q. Are you aware of any mesh design available for use today in the pelvic floor that provides lower contraction rates than the Prolift?

A. There are mesh constructions which are closer to these criteria for mesh design -- for safe mesh design.

Q. Are you aware of any comparative studies which show that there is a mesh available for use in the pelvic floor today that provides lower contracture rates than the Prolift?

A. No comparative studies are available, to my knowledge.

Q. Okay. Can you name one mesh on the market today that you think that the benefits outweigh the risks for use in treatment of pelvic organ prolapse?

A. No. And to answer this question, it is impossible in this general statement. It depends on the patient. It depends on the indication. Then you have to specify which implant under which conditions. So it is not possible to answer this question.

MR. THOMAS: Let's take a break for a second.

THE VIDEOGRAPHER: We are off the record. The time is 12:55 p.m.

(A recess was taken from 12:55 p.m. until 1:00 p.m.)

THE VIDEOGRAPHER: We are back on the record. The time is 1:00 p.m.

BY MR. THOMAS:

Q. Doctor, can you tell the jury one product on the market for the treatment of pelvic organ prolapse that you think is better than the Prolift?

A. In regard to the effective porosity, for example, and the strain, I know that DynaMesh has a device that is superior to the Prolift.

Q. And the DynaMesh is not -- is that the only

one that you think is better for use in the pelvic floor --

A. I know --

Q. -- than the Prolift?

A. I know there is a huge variety. I'm not sure which is -- what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market.

Q. And the DynaMesh is not available for sale in the United States; correct?

A. I think so, but I'm not informed about the --

Q. You think that it is available?

MR. ANDERSON: Let him finish his answer, if you wouldn't find.

Go ahead.

THE WITNESS: I think it is not available, but I'm not knowing all the details which product is in which country on the market.

BY MR. THOMAS:

Q. Let me --

A. I'm not involved in this business.

Q. Let me ask the question this way so it's clear. We had some interruptions.

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You don't know whether DynaMesh, manufactured by FEG, is available for sale in the United States, do you?
A. I don't know.
Q. Okay. And you said that DynaMesh is better than Prolift from the perspective of effective porosity?
A. As we measure it, as we can show with our measurements it has a higher effective porosity, it has a higher stability when put to strain.
Q. But you agree that there are no clinical long-term studies that prove the superiority of the DynaMesh over the Prolift for the treatment of pelvic organ prolapse?
A. There are at all no comparative studies showing the superiority of any of these, and, again, it is not possible to do so. I don't see a good way to do so.
Q. And you're aware of no studies that demonstrate that PVDF mesh, which is DynaMesh, is superior to the polypropylene mesh used in Prolift; correct?
A. We know from many histological studies that the tissue reaction to PVDF is better than the tissue

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reaction to the polypropylene, less inflammation, less scarring when you are using the PVDF.
Q. And the PVDF -- strike that.
You're aware of no studies in humans that demonstrate that PVDF mesh is superior to polypropylene mesh used in Prolift for pelvic floor repair; correct?
A. Our studies in human explants always confirmed the superiority of PVDF as a polymer to be integrated in tissue.
Q. And is this in hernia explants?
A. This is in hernia explants.
Q. And these -- this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection?
A. Yes.
Q. And have you looked at any PVDF mesh explants from the pelvic floor?
A. Up to now I never saw one.
Q. Okay.
A. Which is a good sign.
Q. And just so the record is clear, you don't maintain your own collection of mesh removed from the pelvic floor; correct?

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A. I don't have an own -- at the moment I don't have an own collection of pelvic floor meshes.
Q. You collect hernia meshes; correct?
A. We had collected, but meanwhile the -- all the tissue samples are stored in a biotissue bank from the university from the institute for pathology centrally where they are stored under GCP conditions.
Q. Okay. But you've never asked your department that deals with the pelvic floor to preserve and collect meshes that have been removed in explants; correct?
A. No. It's no longer an issue that I -- that I'm asked to collect these. They are sent all to this bio bank; and when you want to make a research, then you can ask for getting these samples.
Q. Now, to your knowledge, there's only one mesh manufacturer in the world that makes mesh made of PVDF for the treatment of pelvic organ prolapse; correct?
A. In the moment, I think this is true.
Q. And that's FEG?
A. This is true.
Q. And that's the German mesh manufacturer headquartered here in Aachen?

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A. Yes.
Q. And you helped PVDF -- excuse me. Strike that.
You helped FEG develop its PVDF mesh, didn't you?
A. Yes.
Q. And you're named on the patent for PVDF mesh?
A. Yes.
Q. You've done research for FEG since 1994; correct?
A. That is correct.
Q. And Dr. Oberlinski is one of FEG's owners; correct?
A. That is correct.
Q. And he used to work with you at the university; correct?
A. This again?
Q. He used to work -- Dr. Oberlinski used to work at the university, didn't he?
A. When we started our collaboration, he worked for the institute for textile engineering at the university, but then later on he changed to the company.
Q. It was Dr. Oberlinski who first told you that

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there are several textile options available to change mesh?
A. Yes.
Q. Now, you've been a paid consultant by FEG since 1998 or 1999. Is that true?
A. No. I guess it was later on. It was after the contract finished with the -- with Ethicon.
Q. And to this day you're compensated annually by FEG; correct?
A. Correct.
Q. And they pay you about 30,000€ a year?
A. Yeah.
Q. They determine how much they'll pay you each year depending on how well the company does that year; correct?
A. Yes.
Q. And you've spoken at conferences sponsored solely by FEG; correct?
A. Yes.
Q. And you do that routinely? You regularly attend conferences around the world on behalf of FEG; correct?
A. I routinely attend conferences, and I am invited all over the world. Most of these, far most

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of these invitations are not linked to the FEG. So it is an exception if I do it on the -- on the invitation of the FEG. This is a rare exception.
Q. And your picture is on the FEG website, isn't it?
A. Maybe. To be fair, I never have looked to this website. I didn't saw any need to do so.
Q. And you're going to teach next week in Baden-Baden at a class sponsored by FEG, aren't you?
A. Yeah.
Q. The International Masterclass for Laparoscopic Hernia Repair; correct?
A. Yes.
Q. And that's a seminar sponsored by the FEG?
A. Yeah. It was an invitation by Professor Berger, who was the former head of the German Society, and we did it for the fourth time or the fifth time.
Q. And the agenda for the hernia session is on the FEG website, isn't it?
A. As I told you, I'm not a visitor of this website.
MR. THOMAS: That's all the questions I have. Thank you, Doctor.

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MR. ANDERSON: Okay. Take a short break.
THE VIDEOGRAPHER: We are off the record. The time is 1:10 p.m.
(A recess was taken from 1:09 p.m. until 1:31 p.m.)
THE VIDEOGRAPHER: We are back on the record. The time is 1:31.
REDIRECT EXAMINATION
BY MR. ANDERSON:
Q. Dr. Klinge, do you remember when counsel was asking you some questions about the PVDF mesh and PVDF fibers?
A. There has been several questions, but I remember.
Q. Okay. If we could go to Plaintiff's Exhibit 697 right here. It's the Otto article. If we could go over a few pages to the mesh.
MR. ANDERSON: No. Blow up the top part. Actually, no, no. Next page.
MR. KAUFFMANN: Next page?
MR. ANDERSON: Okay. Yeah. Blow up the whole top part.
BY MR. ANDERSON:
Q. Doctor, the mesh on the far right side, the DynaMesh, is that the mesh that you were talking with

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counsel about that's made by FEG?
A. Yes. This is a PVDF mesh made by FEG.
Q. And does FED -- FEG make meshes made out of this PVDF material for pelvic organ prolapse?
A. Yes.
Q. And just explain quickly for the jury what PVDF is as a polymer, as a material.
A. PVDF is a plastic material like -- as polypropylene is, but it has -- it consists of two fewer atoms. So it has some other molecules inside, and it has more stability than the polypropylene.
Q. How long have you known about PVDF as an alternative polymer to polypropylene for surgical meshes?
A. We, actually, started to think about it in 1997. When we finished the Vypro, we knew that it was possible to made a mesh with large pores. But Vypro consists of five filaments, and to reduce further on the risk for bacterial infection, we wanted to construct it as a monofilament. And, therefore, we have been looking for the best material for the construction of a monofilament large pore meshes. And there it came up that PVDF may be the best.

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And we approached Ethicon to join this activity further on. We asked for some grants to do this research, and, fortunately, we got the permission to do this project by our university and we got some further grants to work on PVDF meshes; but, unfortunately, Ethicon denied to develop meshes made of PVDF, though they provided us with one PVDF mesh that is made by Ethicon.

Q. So did Ethicon have an opportunity to work with you and FEG to develop PVDF meshes during this time period?

A. Obviously they had a mesh, but they didn't want to go into this project to develop PVDF meshes, but they were asked, but they denied. They didn't want to do so.

Q. Have you studied the differences in the tissue reaction in patients' tissue of polypropylene versus a PVDF?

A. Yeah. We did a several --

Q. Okay.

MR. ANDERSON: Pull up Plaintiff's Exhibit 770, which may help us with this discussion.

(Plaintiff's Exhibit No. PLT0770, Article

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entitled "New Polymer for Intra-Abdominal Meshes - PVDF Copolymer", was marked for identification.)

BY MR. ANDERSON:

Q. I'm showing you what's been marked as Plaintiff's Exhibit 0770. Is this some of the research that you were just describing where you were looking at tissue response to PVDF?

A. Yes.

Q. Okay. Tell the jury what your conclusions were after looking at this PVDF study.

A. In this study, this study clearly confirms that the tissue reaction to the PVDF is better than for the polypropylene.

Q. Who provided you with the PVDF meshes for testing in this study?

A. It was a PVDF mesh made by Ethicon.

MR. ANDERSON: Let's go to the end of the document under the conclusion section. Go back. There. "This study was supported..."

No. Down below. Next paragraph.

BY MR. ANDERSON:

Q. Is this what you're discussing, that this PVDF study was, in fact, supported and funded by

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Ethicon?

A. Yes.

Q. Okay.

MR. ANDERSON: Let's go to Exhibit 3354. Oh, it's the wrong one. I need the translation.

(Plaintiff's Exhibit No. P3355, English Translation of Plaintiff's Exhibit 3354, Patent for PVDF mesh, was marked for identification.)

BY MR. ANDERSON:

Q. I'm showing you what has been marked as Plaintiff's Exhibit 3355. What is this, Doctor?

A. This is a patent from Ethicon.

Q. Okay. And what's it a patent for?

A. It's a patent for a PVDF mesh.

Q. Is this something that you've reviewed and relied upon in forming some of your opinions here?

A. Yes.

Q. If you'll turn over to page 12.

MR. THOMAS: Show my objection to this witness offering any testimony about this document. It's well beyond the scope of his expertise. The document speaks for itself.

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There's nothing special he can bring to the issues raised by this patent.

MR. ANDERSON: Yeah. And I didn't ask him anything about PVDF on direct. You chose to. You opened the door. We're going to drive through it.

BY MR. ANDERSON:

Q. Okay. So if you will look at page 12 under claims.

A. Yes.

Q. What does it say with regard to the pore sizes for PVDF mesh?

A. Basic structure should have a pore size with a range of 1.5 to 8.0 millimeter, so to be extremely large, covering 90 percent of the total area of the pores.

Q. Okay. Let's go to Plaintiff's Exhibit 1087, which you've already seen. Plaintiff's Exhibit 1087. He can have it. I gave him a copy. Plaintiff's Exhibit 1087.

You're okay. You don't need to go there. It's going to come up on the screen.

Is this a document we reviewed earlier during your direct examination?

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A. Yes.
Q. Okay. From 2008?
A. From 2008. Ethicon document.
Q. Okay.
MR. ANDERSON: If you'd go to the slide.
MR. KAUFFMANN: Got it.
MR. ANDERSON: Yes. Blow up that bottom left.
BY MR. ANDERSON:
Q. In this Ethicon presentation, what is this?
A. This is a PVDF copolymer mesh.
Q. And do you know -- and based upon your review of the patent and your review of these documents, did Ethicon have a brand name for this PVDF mesh?
A. No. I don't think that they marketed it.
Q. No. Not marketed it but --
A. Yeah.
Q. -- did they have a brand name for it?
A. Brand name was Pronova. Pronova was the name of this.
Q. Do you have any information as to whether or not Ethicon ever chose to sell their Pronova mesh made out of PVDF?
A. So far I know, they never brought it to the

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market.
Q. And from your reading of the PowerPoint, what was the discussion and the reason for this PowerPoint being given at Ethicon?
MR. THOMAS: Objection; state of mind, knowledge of Ethicon.
BY MR. ANDERSON:
Q. What was discussed in this Thunder PowerPoint by Ethicon?
MR. THOMAS: Same objection.
THE WITNESS: The entire project was to evaluate whether the use of PVDF would make a safer approach -- would make a safer device for the use in the pelvic floor.

(Plaintiff's Exhibit No. P3184, Letter to Quentin from Christoph Walther, Bates stamped HMESH_ETH_00379723, was marked for identification.)

BY MR. ANDERSON:
Q. Let's look at Plaintiff's Exhibit 3184. This is a document that you have seen before, Dr. Klinge.
MR. ANDERSON: If you'll highlight the section that says "In extremely, this patient,"

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right there.
MR. THOMAS: That's not what it says. I object to showing this document to the jury, admission of this document and any testimony about this document. The document speaks by itself, and this witness is not qualified, with no foundation to give any comment about the document.
BY MR. ANDERSON:
Q. Dr. Klinge, did you, in fact, have this document in your own files when you worked with Ethicon?
A. Yes.
Q. And did you produce that to Ethicon when they requested all of your files?
A. Yes.
Q. So this is a document that you received while you were consulting with them?
A. Yes.
Q. Great. And underneath there it says Christoph Walther. Is that one of the Ethicon employees that you would have worked with?
A. Yes.
Q. And in the middle there where it says,

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"Pronova monofilaments are an extremely good candidate as implant material, very high flexibility and low bending stiffness" --
A. Yes.
Q. -- "and without loss of tensile strength in contrast to polypropylene and long-term stability -- long-term stability in human body."
Do you agree with those statements by Ethicon?
A. Yes.
Q. Do you have an opinion as to whether or not polypropylene mesh is -- creates greater inflammatory reaction in tissues than PVDF mesh?
A. Polypropylene in general produces more inflammation, more scarring than PVDF.
Q. You were asked by Mr. Thomas on cross-examination whether polypropylene has been used in the human body for hernia mesh since 1962. Do you remember that question?
A. Yes.
Q. And has polypropylene been used in the human pelvis of women for pelvic organ prolapse since 1962?
A. No. It's less than ten years.
Q. He also pulled out the -- that 240 meters of

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suture material and asked you whether or not that much material goes into some of the meshes in the hernia -- for hernia repair. Do you remember that part of your questioning?

A. Yes.

Q. Is there a difference between that amount of material in the abdominal wall than that amount of material in a woman's vaginal space?

A. Definitely. The use of a mesh in the abdominal wall, we don't have to consider some forces. It's laying there flat, usually beneath the muscles. You don't have any tension to any arms or something like this. There are less nerves. There are no organs with direct contact to the mesh that can be damaged by this. So it is more easy -- if you have some complications, some infection, it is quite -- much more easy to remove it and to repair the damage after a mesh complication.

Q. Easier to remove the hernia than the pelvic organ prolapse, is that what you're saying?

A. It is easier to remove the mesh.

MR. THOMAS: Let me move to strike his testimony about mesh in the pelvic floor as being beyond the area of his expertise.

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MR. ANDERSON: You sure asked him a lot of questions about it, but okay. Let's move on.

BY MR. ANDERSON:

Q. You were asked some questions about consenting your patients when you were a hernia surgeon. Do you remember that?

A. Yes.

Q. And you were asked questions about what risks you would pass along to your patients; correct?

A. Yes.

Q. Can you pass along a risk if you're not told about it by the manufacturer?

A. No.

Q. If you were a surgeon who's implanting a new surgical device, do you expect the manufacturer to pass along information they have about serious adverse events that could affect that risk-benefit discussion with your patients?

A. Definitely.

MR. THOMAS: Objection; foundation, beyond the scope.

MR. ANDERSON: It's direct response to the cross-exam.

BY MR. ANDERSON:

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Q. Go right ahead, Doctor.

A. When using -- when I would use a new device, I'm dependent on the information that is provided by the manufacturer for the long-term risks or for the risks that are connected to this device. There is no other way to get this information.

Q. If you're a surgeon that's putting in what you characterize as a relatively new device, if the manufacturer knew that there was a serious long-term risk of chronic debilitating pain, would you expect them to pass that information along to you?

A. Yes, I would.

MR. THOMAS: Objection to foundation.

THE WITNESS: And in parallel, he has to stop selling it.

BY MR. ANDERSON:

Q. And if a manufacturer was aware of serious adverse events of life-altering untreatable erosions, would you expect them to pass that along to you as a surgeon?

MR. THOMAS: Objection.

A. Yes.

MR. THOMAS: Argumentative.

BY MR. ANDERSON:

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Q. Okay. Wait until he does his objection --

A. Sorry.

Q. -- and then you can answer because it's messing up the record, and it's harder for her to type.

A. Sorry.

MR. THOMAS: Do you want to ask the question again?

MR. ANDERSON: I think I liked it.

THE COURT REPORTER: You might need to --

MR. ANDERSON: Because he interrupted me?

MR. THOMAS: I didn't want mean to.

MR. ANDERSON: Well, you already did.

MR. THOMAS: I'm sorry. Doing the best I can, man.

BY MR. ANDERSON:

Q. If a manufacturer is aware of serious lifelong risk of recurrent erosions that can't be treated, would you, as a surgeon, want to know that?

A. Yes.

Q. If a manufacturer is aware that their product can create a serious adverse long-term risk of dyspareunia or painful sexual relations, would you expect them to pass that along to you?

A. Yes.
Q. If a manufacturer was aware that in certain patients, like young patients or sexually active patients, that in those patients they shouldn't have that device implanted, would you expect them to pass that along to you?
A. Yes.
MR. THOMAS: Just show my objection to the whole line as being beyond his whole line of expertise as a hernia surgeon.
MR. ANDERSON: And that's fine because, just for the judge's purposes when we go to argue this, Mr. Thomas asked numerous questions about passing on the risk-benefit information and that the manufacturer didn't need to tell him these things because he already knew it; and so let's go through some of the things on redirect of what he would like to know from the manufacturer, and so that's what I'm attempting to do now. So we'll note your objection and my response.
BY MR. ANDERSON:
Q. If the manufacturer is aware that their device should not be used with certain patients, certain indications, would you expect them to pass

that information along to you?
A. Yes.
MR. THOMAS: Objection; vague.
THE WITNESS: Yes, of course.
BY MR. ANDERSON:
Q. For instance, if a manufacturer knew that a particular type of hernia or a particular type of prolapse, it would be inappropriate to treat with that device, would you expect them to pass that along to you?
MR. THOMAS: Objection; compound.
THE WITNESS: Yes.
BY MR. ANDERSON:
Q. Mr. Thomas said something on cross about the Prolift being implanted tension-free. You've seen the DVD; correct?
A. Yes.
Q. You've seen the internal documents by Ethicon?
A. Yes.
Q. Is there any way that a Prolift can actually be implanted tension-free in a woman?
MR. THOMAS: Objection; not an expert in the surgical procedure.

THE WITNESS: There is no way to place it completely tension-free, and I believe there is no one who will really think of it as an option.
BY MR. ANDERSON:
Q. When you saw those arms being pulled through the woman's groin from her vaginal incision, was there tension being placed on those arms?
A. Definitely. Uniaxial tension, as it was done in our measurements and it was done -- as it was done in the drawings from Ethicon and in the study done by Ethicon.
Q. And Mr. Thomas mentioned that when you did your uniaxial testing with Professor Mühl that you held one end and you pulled on the other end; correct?
A. Yes.
Q. Is that exactly what the surgeon was doing in that DVD video with the arms?
A. Yes.
Q. You were asked some questions about your testing with Professor Mühl by Mr. Thomas about whether or not this -- the porosity setup and investigation you had done accounted for pelvic floor forces. Do you remember that?

A. Yes.
Q. As you looked at the pores in the DVD and the tension placed on the mesh arms by the surgeon, are those pores deformed before any forces from the pelvis are being placed on the mesh?
MR. THOMAS: Objection. Again, not familiar with the surgical procedure and what's going on inside.
THE WITNESS: In these arms there is no interference with some other forces from the pelvic floor, and there is no interference with some ingrowing tissue which will occur later on.
BY MR. ANDERSON:
Q. So were the pores irreversibly deformed on a Prolift arm even before the woman's vaginal incision is closed?
A. Yes.
MR. THOMAS: Objection. That's beyond the scope of this witness's ability to testify, any expertise, any disclosed opinions or testing.
BY MR. ANDERSON:
Q. And your answer was?
A. Yes.
Q. Thank you.

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He also -- Mr. -- the counsel also pointed out from these articles -- he pointed out to two sections on the 2007 article and the 2013 article, these sections that says clinical studies have to prove whether or not effective porosity and meshes with high effective porosity will actually result in improved patient complications. Do you remember that?

A. Yes.

Q. And he asked you, "You haven't done any clinical studies to look at this, have you?" Do you recall that question?

A. Yes.

Q. Are you a mesh manufacturer, Doctor?

A. No.

Q. After Ethicon circulated these two e-mails in 2008 and again in 2010, circulating your and Mühl's testing, did you see anywhere in the Ethicon documents where they did any clinical studies to look at pore deformation?

A. No, I didn't find any hint for this.

Q. Do you see anywhere in the documents, all the thousands of documents you reviewed, all the depositions of all the Ethicon witnesses you

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reviewed, or any scientific literature where Ethicon ever looked at what the impact on patients would be after forces were placed on the arms? Do you see that anywhere?

A. No.

Q. You were asked why your machine was set for 1,000 microns for polypropylene in terms of a critical limit of the distance between the fibers, and you were asked why PVDF was set at 600 microns. Do you remember that?

A. Yes.

Q. Why?

A. The basis for these two figures, 600 and 1,000 microns, have been our investigations of the tissues, because we have seen that around the fiber made of PVDF, the inflammatory reaction is -- is attenuated and there is less scar and that the pores are filled with fat even when the size of the hole of the pore is only 600 microns. And, therefore, because this -- this measurement by Professor Mühl was intended to predict the risk for these scar contraction and scar integration in the pores; therefore, we adopted this to 600 microns for PVDF and 1 millimeter for polypropylene. It fits to our

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experimental results. And if you have another polymer, yeah, you have to adopt it to this polymer after having the -- making this investigation.

Q. Thank you. Let me go to another question he -- series of questions you were asked.

He put two articles in front of you by Jan Deprest, and counsel said, "Are you aware of other scientists out there who may disagree with your 1 millimeter?" Do you remember that part of the questioning?

A. Yes.

Q. Those two articles by Jan Deprest, is Jan Deprest an Ethicon consultant?

A. So far I know, yes.

Q. And if Jan Deprest said that 75 microns is efficient for good, healthy tissue ingrowth and it will resist scar plates, is that consistent or inconsistent with Ethicon's own documents?

MR. THOMAS: Object to the form of the question. Object to foundation.

THE WITNESS: It will be inconsistent. If you really believe that it is possible to -- or the ingrowths of healthy tissue is possible for these low pore size, then it would be

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inconsistent. The Ethicon people clearly stated it on several pages in several documents that we have to consider a pore size of 3 millimeters or at least 1 millimeter and far beyond.

BY MR. ANDERSON:

Q. And was the product that was developed by you and Ethicon, the Vypro mesh, did it have pore sizes less than 75 microns?

A. No.

Q. Did it have pore sizes larger than 1,000 microns?

A. So the pores -- the area of the large pores is considerably higher, and the diameter of these pores is between 3 and 5 millimeter.

Q. Have you seen anywhere in the Ethicon documents out of all of the ones you've reviewed or out of the ten years of consulting with them or all of the depositions that you saw anywhere where Ethicon said, "At 75 microns we can prevent fibrotic bridging"?

A. Nowhere.

Q. You were asked another series of questions about whether there were any RCTs that you could point to randomized controlled trials of Prolift in

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order to prove the safety of its device. Do you remember that?
A. Yes.
Q. You were asked whether you had conducted any studies or knew of any studies, randomized controlled trials, to prove the safety of Prolift. Do you remember that?
A. Yes.
Q. Do you see anywhere where Ethicon conducted their own safety studies in order to look as to whether or not this amount of material was actually necessary to support a woman's pelvic organs?
A. No.
Q. Did you see anywhere where Ethicon did any clinical trials to determine whether or not the pore sizes of Gynemesh PS were necessary to be that size in order to support pelvic organ prolapse?
A. No.
Q. Did you see anywhere where Ethicon justified or clinically studied that it was necessary for them to have pores that would collapse and look like the deformed pores on the DVD in order to be safely implanted in a woman?
MR. THOMAS: Objection; argumentative.

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BY MR. ANDERSON:
Q. Did you see that?
A. No.
Q. You were asked a whole lot of questions about this 91-day rat study, so let's talk about a rat study if we could. That was an internal Ethicon study; correct?
A. Yes.
Q. Done by Ethicon scientists?
A. Yes.
Q. Was it peer-reviewed in the peer-reviewed publications?
A. No.
Q. The size of the piece of mesh, can you just show the jury what the size of the piece of mesh would be that went into the back of these little rats?
A. It's usually the size of the fingertip or the nail.
Q. Okay. So we have a piece of mesh the size of our fingernail going into the back of a rat for 91 days. That's what this study was; correct?
A. Yes.
Q. Is that going into healthy tissue?

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A. It's healthy tissue in healthy rats.
Q. Is it being used with trocars and cannulas to pull it in there?
A. No trocars.
Q. Is it going in through a transvaginal incision of the rat?
A. No, nothing like this.
Q. Is it being permanently implanted in the rat's tissue?
A. It's only implanted for 90 days.
Q. Were any forces placed on the mesh during the implanting or being forced -- any forces on the mesh after implantation?
A. No. When placing in the subcutaneous area, you don't have any forces.
Q. Is the subcutaneous skin in the back of a rat the same as the delicate pelvic tissues of a woman?
A. No. It is -- the tissue reaction of pure fat is attenuated.
Q. When Prolift or any other pelvic organ prolapse mesh is put into a woman's tissue, is that because it's healthy or unhealthy?
MR. THOMAS: Objection.
THE WITNESS: Unhealthy.

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BY MR. ANDERSON:
Q. And is it being permanently implanted or implanted for 91 days?
A. It's permanently for years hopefully.
Q. And are these rats having sexual relations while they have the mesh in their back?
MR. ANDERSON: I would like to withdraw that question.
THE WITNESS: I think so.
BY MR. ANDERSON:
Q. Let me ask you this, Doctor.
Would it be safe to take a three-month study of a piece of mesh that's the size of your fingernail that was in the back of a rat where no trocars were used in healthy tissue, not going through a transvaginal incision, with no forces placed on the mesh, in order to say this study will tell you that Prolift can be safely implanted in a woman's vagina for the rest of her life?
A. It would be very dangerous to take this study as a proof for safety. This is not justified. And if you'll remember to the results, there wasn't no -- there wasn't a significant difference among the meshes. Meanwhile, you have hundreds of studies

showing that the material has an impact on the tissue ingrowth. So if you make your own study and seeing no difference in these small group of animals, then you should think of exchanging the people who are responsible for this study. It is -- yeah.

Q. So counsel asked you on cross-examination -- he said, "You have not designed a device that was designed for the -- for pelvic organ prolapse." Do you remember that question?

A. I remember it.

Q. Has Ethicon ever designed a mesh that was specifically designed for the pelvic floor?

A. No.

Q. You were asked three different questions that I want to go to, Doctor. You were asked at the beginning of your cross-exam, "91 percent of all surgical meshes on the market today are made of polypropylene." Do you remember that question?

A. Yes.

Q. And do you remember the question of, "Can you think of any product on the market today that is safer than Prolift for pelvic organ prolapse?" Do you remember those questions?

A. Yes.

Q. Is Prolift or Prolift+M still on the market today?

MR. THOMAS: Objection.

THE WITNESS: So far I know, it is not longer on the market.

MR. ANDERSON: I don't have any other questions.

MR. THOMAS: We need to consult.

THE VIDEOGRAPHER: We are off the record. The time is 2:01 p.m.

(A recess was taken from 2:01 p.m. until 2:02 p.m.)

MR. THOMAS: That's all the questions I have.

(Whereupon, the deposition concluded at 2:02 p.m.)

CERTIFICATE

I, Tami Cline, Registered Merit Reporter, Certified Realtime Reporter, and Florida Professional Reporter, do hereby certify that, pursuant to notice, the deposition of PROF. DR. MED. UWE KLINGE was duly taken on November 10, 2014, at 9:04 a.m. before me.

The said PROF. DR. MED. UWE KLINGE was duly sworn by me according to law to tell the truth, the whole truth and nothing but the truth and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me. I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

_____

Tami Cline, RMR, CRR, FPR

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby acknowledge that I have read the foregoing pages, 1 to 224, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

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PROF. DR. MED. UWE KLINGE DATE

Subscribed and sworn to before me this

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